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(54) Title: METHOD FOR MANUFACTURING BEADS CONTAINING EXOGENOUS SOY PROTEIN

(57) Abstract: The present invention provides protein-containing particles with a high eating quality characterised by having a high content of exogenous protein and optionally of phospholipids and/or of fibres. The present invention also procides a mehtod for manufacturing protein-containing particles with a high eating quality characterised by having a high content of exogenous proteins and optionally of phospholipids and of fibres. The present invention further provides soy protein-containing beads, methods for the manufactureof same and bread comprising soy protein-containing beads and methods for the manufacture of same.

METHOD FOR MANUFACTURING BEADS CONTAINING EXOGENOUS SOY PROTEIN

FIELD OF THE INVENTION

The present invention concern protein containing particles containing exogenous soy protein and having an improved eating quality and also concern methods for manufacturing protein containing particles containing exogenously added protein and having an improved eating quality. In a particularly preferred embodiment the present invention relates to soy protein containing beads the manufacture of same bread comprinsing soy protein containing beads and the manufacture of same. Furthermore, the present invention relates to soy protein, phytoestrogens, phospholipids, and dietary fibers and protein containing particles incorporating same suitable for preventing, treating and/or alleviating cardiovascular diseases such as hypercholesterolemia, hypertriglyceridemia, hyperlipidemia, arteriosclerosis, hypertension and related cardiovascular diseases, for preventing and/or treating type 2 diabetes and/or the metabolic syndrome, and for preventing, treating and/or alleviating pulmonary diseases. The present invention also pertains to the use of such protein containing particles in the prevention and/or treatment of a cardiovascular disease in a subject suffering from type 2 diabetes

A protein particle according to the present invention is particularly useful in preventing and/or reducing the influx of triglycerides and/or cholesterol into the arterial wall and/or reducing the accumulation of cholesterol in the arterial wall of subjects at high risk for developing cardiovascular disease or subjects already suffering from a cardiovascular disease such as atherosclerosis or diabetic subjects. A protein particle according to the present invention is also useful for lowering serum levels of total cholesterol and/or LDL-cholesterol and/or triglycerides and/or homocystein and/or for increasing serum levels of HDL-cholesterol and/or for improving the serum HDL/LDL-ratio in subjects at risk for developing cardiovascular diseases and in subjects already suffering from an arteriosclerotic condition such as e.g. atherosclerosis or a related cardiovascular disease. A protein particle according to the present invention is also useful in lowering serum levels of total cholesterol and/or LDL-cholesterol and/or triglycerides and/or glucose and/or increasing serum levels of HLDL-cholesterol in diabetic subjects. A protein particle according to the present invention is also useful in treating e.g. chronic obstructive pulmonary disease (COPD), inflammation of the airways, asthma, bronchoconstriction, bronchitis, and small airways disease.

The present invention also concerns use of protein containing particles according to the present invention in the prevention and/or treatment of said diseases and disorders and for lowering serum levels of total cholesterol and/or LDL-cholesterol and/or triglycerides and/or homocystein in subjects. In addition, the present invention also provides methods for preventing, treating, prophylactically treating and/or alleviating by therapy said diseases and disorders.

BACKGROUND OF THE INVENTION

The field of functional foods has increased tremendously in recent years as the health awareness of the population in the industrialised parts of the world has gone up coincident with an increase in lifestyle related syndromes such as obesity, cardiovascular diseases and type II diabetes. Several studies show a significant correlation between the diet of a subject and the risk of the subject of contracting one or more of these diseases and syndromes. This has put the spotlight on the healthiness of everyday diet and as research into the field continues many items are added to the group of ingredients that should be present in a healthy diet. Functional foods can be defined as ordinary food items, which include one or more ingredients that can be beneficial to human health in one way or another. Functional foods can for instance be diary products, such as cultured dairy products.

Intake of soy protein, either alone or in combination with other soybean components, has been shown to have several beneficial effects on humans. Naturally, the soy protein could be consumed by eating soybeans, but this has little appeal, as soybeans are conceived by some to have an objectionable flavour and furthermore are not part of a traditional diet in the Western world. An alternative way of consuming soy protein is as part of a functional food product containing soy protein.

Traditionally there has been an upper limit as to how much exogenous protein a food product could contain without adversely affecting for example the flavour, texture, mouthfeel, taste or features important for the manufacturing process such as process time etc. Exogenous protein can for example be incorporated in food products in the form of particles. This has been described in a number of patents such as e.g.

GB1522439 concerns bakery products which have been prepared by the use of debittered soy grits in which trypsin-inhibitor has been substantially deactivated or removed. The average size of the soy grits is preferably at least 0.2 mm, more

preferred from 1 to 8 mm and the soy grits are preferably bruised or crushed grains. In addition to the soy grits the bakery products of the invention may be prepared by the use of a protein extract, such as soy flour preferably in an amount of 10-20% by weight of the dry ingredients.

JP19770063225 concerns a method for the manufacture of granular defatted soybean protein without specific soybean taste and flavour. The granular soybean protein is prepared by mixing defatted soybean having a protein content of 40-70%, usually 50%, with water to obtain a dough with a moisture content of 25-40% and extruding the dough at 120-200°C at 20-60kg/cm2 followed by cutting, granulating and drying to a moisture content of <10%, preferably 6-8%. The undesirable taste and flavour is removed by washing >4 times with an aqueous ethanol solution, at 50-70°C.

The article "Extruded soy products from whole and dehulled soybeans cooked at various temperatures for bread and cookie fortifications", Cereal Foods World, (1975) 20(9) 413-418, descibes the use of extrusion-cooked products, directly in the form of flakes, or following a roller-mill grinding. Acceptable products containing 12% of the soy products were obtained.

Soy protein containing particles with exogenously added protein which result in food products with improved eating quality and improved health benefits have however not been described.

It is thus the aim of the present invention to provide such protein containing particles and food proucts and to provide methods for the manufacture of both. In part it is a further aim of the present inveniton to provide soy protein containing beads methods for the manufacture of same and bread comprising soy protein containing beads and methods for the manufacture of same.

SUMMARY OF THE INVENTION

The present invention provides protein containing particles with a high eating quality characterised by having a high content of exogenous protein and optionally of phospholipids and/or of fibres. The present invention also provides a method for manufacturing protein containing particles with a high eating quality characterised by having a high content of exogenous proteins and optionally of phospholipids and of fibres. The present inveniton further provides soy protein containing beads methods

for the manufacture of same and bread comprising soy protein containing beads and methods for the manufacture of same.

Said methods for the manufacture of bread or food products are further characterised by employing a blend of exogenous protein and optionally phospholipids and/or fibres for the preparation of beads, which may be hydrated prior to incorporation into the food product or the dough. According to said method additional liquid may also be added to the food product or the dough. It is believed that the hydration of the blend or the beads and the adjustment of the amount of liquid added to the food product or the dough counteracts the negative effect of hydrocolloids and proteinaceous material on protein containing particles quality. Such negative effects will be more pronounced if the protein containing particles further comprises high amounts of fibre. It is known that water has to be absorbed by the protein in the wheat flour in order to allow its transformation into gluten. If absorbent material is added to a formulation of a protein containing particles it takes away water from the protein, thereby reducing gluten development with the effect of impairing the quality of the baked bread.

Intake of a protein enriched protein containing particle according to the invention will provide any beneficial effects associated with the exogenously added proteins. Furthermore, a protein enriched food product based on protein containing particles according to the present invention will be able to comply better with consumer-expectations than food products prepared by use of previously available methods for protein fortification of food products, since food products with an increased eating quality is obtained by the hydration of the soy blend-based particles and the adjustment of the amount of liquid added to the dough or the food product. In addition, food products comprising soy tend to preserve moisture for longer periods than traditional food products, resulting in improved shelflife.

In one aspect, the present invention provides protein containing particles with a high eating quality characterised by having a high content of exogenous proteins and optionally of phospholipids and/or of fibres.

In another aspect, the present invention provides a method for manufacturing protein containing particles with a high eating quality characterised by having a high content of exogenous proteins and optionally of phospholipids and of fibres. Said method is further characterised by employing a blend of exogenous protein and optionally

phospholipids and/or fibres, which may be hydrated prior to incorporation into the dough. According to said method additional liquid may also be added to the dough.

In another aspect, the present invention provides a food product comprising protein containing particles prepared by a method according to the present invention.

In yet another aspect, the present invention provides the use of a protein containing particles product with a high eating quality characterised by having a high content of soy proteins and optionally of phospholipids and/or of fibres for lowering serum levels of glucose and/or total cholesterol and/or LDL-cholesterol and/or triglycerides and/or homocystein and/or for increasing serum levels of HDL-cholesterol and/or the serum HDL/LDL-cholesterol ratio in a subject.

The exogenously added protein may be any type of protein or any combination of proteins and may consequently be provided by any protein source or by a combination of protein sources. Examples of exogenously added proteins in the context of the present invention are vegetable proteins, such as soy proteins, and animal proteins. The exogenously added protein is preferably soy protein. The soy protein is preferably provided by isolated soy protein, soy protein concentrate, soy flour or the like or any combination thereof. (The soy protein is preferably provided by isolated soy protein).

Isolated soy protein is the major proteinacious fraction of soybeans. It is prepared from high quality, dehulled, defatted soybeans by removing a preponderance of the non-protein components resulting in an isolated soy protein fraction which shall contain at least 80 (90) percent protein on a moisture free basis. Soy protein concentrates are made by removing most of the oil and water-soluble non-protein constituents from defatted and dehulled soybeans. In the present context a soy protein concentrate shall preferably contain at least 65 (70) percent protein on a moisture-free basis. The soy protein may also be provided by soy flour, which may be full-fat or defatted soy flour. Full-fat soy flour comes from whole, dehulled soybeans that have been ground into a fine powder and, as the name implies, still contains the fat naturally found in soybeans. Defatted soy flour comes from whole, dehulled, defatted soybeans that have been ground into a fine powder. Soy flour contains approximately 50 percent protein on a dry weight basis in the present context.

Preferred isolated soy protein products are supplied by Protein Technologies International, Inc. (under the brand name of *SUPRO®.)* A presently preferred quality is FXP HO 161, but the protein source may be another quality or a mixture of different qualities.

A protein source for use in a method according to the present invention comprises the source or sources of exogenously added proteins. The amount of protein in a protein source for use in a method according to the present invention and the amount of the protein source is preferably such that the amount of exogenously added protein in the resulting food product is at least about 5 weight percent, such as at least about 6 weight percent, for example at least about 7 weight percent, such as at least about 8 weight percent, for example at least about 9 weight percent, such as at least about 10 weight percent, for example at least about 11 weight percent, such as at least about 12 weight percent, for example at least about 13 weight percent, such as at least about 14 weight percent, for example at least about 15 weight percent, such as at least about 16 weight percent, for example at least about 17 weight percent, such as at least about 18 weight percent, for example at least about 19 weight percent, such as at least about 20 weight percent, for example at least about 25 weight percent, such as at least about 30 weight percent, for example at least about 35 weight percent, such as at least about 40 weight percent, for example at least about 45 weight percent.

Optionally, protein containing particles according to the present invention may also comprise exogenously added dietary fibres. Examples of dietary fibres include fibres from apples, oats, and soybeans. The dietary fibres are preferably provided by soybean fibres, and more preferably by soy cotyledon fibres. Preferred soy cotyledon fibre products are supplied by Protein Technologies International, Inc. under the brand name of FIBRIM®. Among the various soybean fibres produced under the FIBRIM® brand, FIBRIM® 1020 is particularly preferred in the present invention. This product also contain soy protein in an amount of 12.4%. Other products of the FIBRIM® brand such as e.g. FIBRIM® 2000 or mixtures of fibre products may also be used.

Dietary fibres may optionally be incorporated in the resulting protein containing particles in an amonut of at least 0.9 weight percent, such as at least about 1 weight percent, for example at least about 1.1 weight percent, such as at least about 1.2 weight percent, for example at least about 1.3 weight percent, such as at least about

1.4 weight percent, for example at least about 1.5 weight percent, such as at least about 1.6 weight percent, such as at least about 1.7 weight percent, for example at least about 1.8 weight percent, such as at least about 1.9 weight percent, for example at least about 2 weight percent, such as at least about 2.5 weight percent, for example at least about 3 weight percent, such as at least about 3.5 weight percent, for example at least about 4 weight percent, such as at least about 4.5 weight percent, for example at least about 5 weight percent, such as at least about 5.5 weight percent, for example at least about 6 weight percent, such as at least about 6.5 weight percent, for example at least about 7 weight percent, such as at least about 7.5 weight percent, for example at least about 8 weight percent, such as at least about 8.5 weight percent, for example at least about 9 weight percent, such as at least about 9.5 weight percent, for example at least about 10 weight percent, such as at least about 15 weight percent, for example at least about 20 weight percent, such as at least about 25 weight percent.

A protein source for use in a method according to the present invention may also optionally comprise carbohydrate sources, fat sources, flavouring agents, vitamins, minerals, electrolytes, trace elements and other conventional additives and the like. If a fat source is present in a protein source for use in a method according to the present invention, a preferred fat source is lecithin, especially soy lecithin. When lecithin, or soy lecithin, is present in a protein source for use in a method according to the present invention, it is usually present in an amount of from about 0.5 to 10 weight percent, preferably from about 2.5 to 6 weight percent of the total protein source.

Preferred examples of protein sources for use in a method according to the present invention are the compositions described in WO 97/31546, which are hereby incorporated by reference. Said patent application discloses compositions comprising (a) isolated soy protein, (b) soybean fibres, preferably soy cotyledon fibres, the amount of (a) being such that the protein content provides at *least 15%* of the total energy content of the composition, and the weight ratio between (a) and (b) being at least *2, preferably at least 3.* These compositions are useful for lowering serum levels of cholesterol and triglycerides and for increasing the HDL/LDL-cholesterol ratio in subjects and for treating obesity.

Additionally preferred examples of protein sources are the compositions described in *PCT/IB99/01992, PCT/IB99/01997 and PCT/IB99/01998.* Said patent applications disclose compositions comprising (a) a soy protein source, selected from isolated soy

protein, soy protein concentrate, or soy flour, of which isolated soy protein is most preferred, said soy protein source providing an amount of soy protein, which is at least 45 weight percent of the total protein content of the composition, preferably at least 50 weight percent of the total protein content of the composition, said total protein content providing at least *15 percent* of the total energy content of the composition, (b) at least one phytoestrogen compound in an amount of more than 0.10 weight percent of the soy protein content of the composition, and (c) dietary fibres, preferably soybean fibres, more preferably soy cotyledon fibres, in an amount of more than 4 weight percent of the total weight of the composition on a dry basis. These compositions are particularly useful for lowering serum levels of total cholesterol, LDL-cholesterol, triglycerides, homocystein, reducing the influx of cholesterol and/or triglycerides into the arterial wall, reducing the amount of oxidized LDL-cholesterol present in the arterial wall, increasing the serum HDL/LDL-cholesterol ratio and/or the serum level of HDL-cholesterol in a subject, including a diabetic subject, reducing and/or eliminating mucus hypersecretion and/or dyspnea in a subject suffering from asthma and/or increasing FEV1 of a subject as measured by forced expiratory volume in the first second of expiration. An example of these compositions is shown to be able to lower serum levels of *inter alia* LDL-cholesterol with as much as 13%. These compositions may therefore be effective in preventing, treating, prophylactically treating and/or alleviating diseases such as cardiovascular diseases, type II diabetes, cardiovascular diseases in diabetics, the metabolic syndrome and pulmonary diseases as described in said applications.

One embodiment of the present invention provides methods by use of which the above-mentioned protein containing particles may be incorporated into food, in amounts, which methods result in food products with increased amounts of exogenously added soy protein. Intake of food products containing protein containing particles according to the present invention will provide the beneficial effects associated with said compositions. Furthermore, a food product prepared by a method according to the present invention will be able to comply better with consumer-expectations than food product prepared by use of previously available methods for protein fortification of food product.

One aspect of the present invention provides the use of *protein containing particles products* as described in the above paragraph for lowering serum levels of glucose and/or total cholesterol and/or LDL-cholesterol and/or triglycerides and/or homocystein

and/or for increasing serum levels of HDL-cholesterol and/or the serum HDL/LDL-cholesterol ratio in a subject.

The present invention provides a particles comprising a protein source, preferably having a high, fixed amount of a phytoestrogen compound such as e.g. naturally occurring isoflavones, and a phospolipid source. More particularly the present invention provides particles on basis of soybean extractable ingredients comprising soy lecithin, preferably having a high fixed level of phosphatidyl choline, and having a high, fixed amount of a phytoestrogen compound such as e.g. naturally occurring isoflavones.

The present invention provides particles comprising a) soy protein, preferably isolated soy protein, b) a high content of a plant hormone in the form of a phytoestrogen compound, preferably naturally occurring isoflavones, (c) a phospholipid source, more preferably lecithin, and even more preferably soy lecithin and preferably having a high fixed level of phosphatidyl choline and optionally (d) dietary fibers, preferably soybean fibers, more preferably soybean fibers manufactured from the cotyledon of soybeans hereinafter referred to as soy cotyledon fibers and the present invention furthermore represents a potential new breakthrough in the treatment of cardiovascular diseases, diabetes and pulmonary diseases.

Particles according to the present invention are useful in prophylactically treating cardiovascular diseases such as hypercholesterolemia, hypertriglyceridemia, hyperlipidemia and other cardiovascular diseases such as e.g. arteriosclerosis. It is one objective of the present invention to significantly lower levels of total serum cholesterol and LDL-cholesterol and triglycerides in a mildly hypercholesterolemic subject. It is another objective of the present invention to significantly lower serum levels of total cholesterol and/or LDL-cholesterol and/or triglycerides in a subject suffering from hypercholesterolemia and/or hyperlipidemia. It is another objective of the present invention to render the arterial wall more resistant to the accumulation of lipoproteins. It is a further objective of the present invention to provide a protein particle effective in preventing, treating, prophylactically treating and/or alleviating an arteriosclerotic condition by reducing the influx of cholesterol and/or triglycerides into the endocelium of the arterial wall and/or by causing the dilation of blood vessels. Yet another objective of the present invention is to reduce lipid plaque formation.

The present invention is also useful in the prevention and/or treatment of type 2 diabetes and/or a cardiovascular disease in diabetic subjects. Accordingly, it is an objective of the present invention to effectively lower serum levels of both glucose and cholesterol and/or triglycerides. No treatment is currently available for concomitantly lowering serum levels of glucose as well as lipid serum levels of total cholesterol and/or LDL-cholesterol and/or triglycerides. It is to be understood that diabetic subjects according to the present invention have a fasting plasma glucose ≥ 7.0 mmol/l.

A soy protein particle according to the present invention represents a new approach to treatment of type 2 diabetes and is believed to be capable of i) lowering total serum levels of cholesterol and/or LDL-cholesterol and/or triglycerides and/or increasing serum levels of HLDL-cholesterol, ii) increasing glucose tolerance and/or insulin sensitivity and/or, iii) lowering serum levels of glucose, iv) preventing, treating and/or alleviating impaired glucose tolerance and/or insulin secretory failure in diabetic subjects and/or v) preventing, treating and/or alleviating an arteriosclerotic condition by reducing the influx of cholesterol and/or triglycerides into the endocelium of the arterial wall of a diabetic subject suffering from a cardiovascular disease and/or by causing the dilation of blood vessels. No other known soy protein containing particles are effective in lowering serum levels of both lipids and glucose and/or reducing the influx of lipids such as e.g. cholesterol and/or triglycerides into the arterial wall.

The present invention is also useful in the prevention and/or effective treatment of pulmonary diseases such as e.g. airway inflammation, asthma, bronchitis and small airways diseases, in particular asthma including chronic asthma such as e.g. asthma characterized by a chronic inflammatory condition. The present invention is believed to be capable of increasing FEV_1 of a subject, measured by forced expiratory volume in the first second of expiration, as well as being capable of treating, alleviating and/or eliminating in particular i) inflammation of the airways, ii) mucus hypersecretion, and iii) bronchoconstriction.

Phytoestrogen compounds are naturally occurring plant hormones showing a structural similarity to 17β-estradiol. Phytoestrogens consist of a number of classes including isoflavones, coumestans, lignans and resorcylic acid lactones. The class of isoflavones consists of among others genistein, daidzein, equol, glycitein, biochanin A, formononetin, and O-desmethylangolesin. The isoflavones genistein and daidzein are found almost uniquely in soybeans. When present in the plant the isoflavones are

mainly in a glucoside form, i.e. attached to a sugar molecule. Isoflavones in this glucoside form can be deconjugated to yield isoflavones in a so-called aglycone form, which is the biologically more active form of isoflavones and which is absorbed faster and to a greater extent in the human gut than isoflavones in the glucoside form. *In vitro* studies have examined the relative estrogenic effect exerted by various phytoestrogens including isoflavones. The resulting potencies as compared to estradiol (having a relative potency of 100), have been reported by Knight (Maturitas 22, 167-175 (1995)) for among others genistein (0.084) and daidzein (0.013). However, the results also showed that the estrogen receptor complexes formed by estradiol and isoflavones such as genistein and daidzein are functionally equivalent. The comparative dissociation constant of genistein for the estrogen receptor, as determined in competitive binding assays, was found to be from 100 to 10.000 times higher than that of estradiol.

Soy proteins are involved in a reduction of cholesterol and triglyceride levels, they are easily digestible, and they represent an efficient sole protein source for maintaining the nitrogen balance. Soy isoflavones in high intakes further enhances this effect. Phospholipids, such as soy lecithins, especially soy phosphatidyl choline have been shown to effect total serum cholesterol levels and/or to increase serum HLDL-cholesterol levels. Dietary fibers, such as soybean fibers, especially soy cotyledon fibers have been shown to lower total serum cholesterol levels, to improve glucose tolerance, to increase insulin sensitivity, to normalize the gastrointestinal function, and to exert no influence on the absorption of essential minerals.

The term "naturally occurring" substance as used in the present specification refers to a substance originally isolated from a natural source, such as an animal or a plant, for example a soy plant, or modified forms of such a substance. The naturally occurring substance for use in a soy protein particle according to the present invention may be included in a food product according to the present invention as part of the natural source or in any type of extract, isolate or the like thereof, or it may have been isolated from a plant source or synthesized biologically, microbiologically, or chemically or by any other means.

The terms "exogenously added protein" and "exogenously added dietary fibres" as used throughout the present specification and the appended claims shall be taken to mean protein or dietary fibres which are not part of the flour for use in a method according to the present invention as such, but which ends up in soy protein particle

by virtue of having been added to or being among or present in the starting materials or the intermediate products in a process for manufacturing said bread, in this case for instance the protein source for use in a method according to the present invention.

The term "protein source" as used throughout the present specification and the appended claims shall be taken to mean a composition comprising protein. For the purpose of the present invention, a protein source may be the source of any number of proteins of any origin. The term itself shall provide no limitations as to the amount of protein present in the protein source and a protein source for use in a method according to the present invention may additionally comprise any number of non-protein components.

DETAILED DESCRIPTION OF THE INVENTION

Soy protein containing particles according to the present invention may be produced using any soy protein source. However, according to a currently preferred embodiment, the soy protein containing particles are produced using a soy blend.

A protein containing particle according to the present invention may be prepared by the addition of all the constituents in a soy blend which is subsequently formed to particles. The soy protein containing particles according to the invention can vary porous to solid. The particles should be mechanically hard in not easy to break in dry state. When the particles comes into contact with water, or when added to a dough, the particles slowly absorb water and swell, but they do not disintegrate or dissolve. Their odour and flavour is neutral or has a small note of soy.

The soy protein containing particles according to the invention are characterized by having a particle size of 100 to 20000 micron, such as 200 to 15000 microns, for example 300 to 14000 microns, such as 400 to 12000 microns, for example 500 to 10000 microns, such as 600 to 9000 microns, for example 700 to 8000 microns, such as 800 to 7000 microns, for example 900 to 6000 microns, such as 950 to 500 microns, for example 1000 and 4000 microns.

If the particles according to the invention are used as an ingredient in bread a particularly preferred size is between 300 to 800 microns.

If the particles according to the invention are used as an ingredient in bars a particularly preferred size is between 200 and 700 microns. In this case it is also particularly preferred to use a mixture of particles according to the invention, with various sizes and bulk densities.

The soy protein containing particles according to the invention are characterized by having a bulk density of 50 to 2000 gram per liter, such as 100 to 1800 gram per liter, for example 125 to 1600 gram per liter, such as 150 to 1500 gram per liter, for example 175 to 1400 gram per liter, such as 200 to 1300 g per liter, for bars: preferably between 200 and 700 microns.

Preferred mehtods for the manufacture of soy protein containing particles according to the invention are:

Alternative A:

a) Use of a not denatured soy protein in the form of an ISP or a soy flour, flakes or similar. The soy powder is mixed with soy fiber, soy lecithin and 10 to 25 % wheat starch, salt and maximum 4 % of maltodextrine.

b) The beads are produced as extruded particles in a traditional extruder. Water used during the process: 20-35 % in total. Temperatures on the barrel: maximum 90 °C and the temperature of the die: maximum 105 °C.

c) The particles are dried in a fluid bed drier, on a belt dryer or in a trey dryer. Conditions:

Air temperature: maximum 60 °C

Vacuum can also be applied.

Alternative B: (much less heat applied during processing):

a) Use of a not denatured soy protein in the form of an ISP or a soy flour, flakes or similar. The soy powder is mixed with soy fiber, soy lecithin and 4-8 % maltodextrine and salt.

b) The mixture is mixed thoroughly by adding a water solution with pregelled starch, guar gum and SSL (maximum 15 % solution) in a closed twin screw mixer. The agglomeration additive can alternatively be added to the powder mixture and with only water added during the agglomeration. The wet material is pressed through a plate

with suitable holes to fit the wanted size on the beads. Temperature on the material at the outlet end is maximum 55 °C.

c) The particles are dried in a fluid bed drier, on a belt dryer or in a trey dryer. Conditions:

Air temperature: maximum 60 °C

Vacuum can also be applied.

A controlled Maillard reaction during processing is preferred.

According to a presently preferred embodiment of a method for producing soy protein containing particles according to the invention the soy powder is mixed with 11 to 24 % wheat starch, such as 12 to 23 % wheat starch, e.g. 13 to 22 % wheat starch, such as 14 to 21 % wheat starch, e.g. 15 to 20 % wheat starch, such as 16 to 19 % wheat starch, e.g. 17 to 18 % wheat starch.

According to a presently preferred embodiment of a method for producing soy protein containing particles according to the invention the soy powder is mixed with 5-7% of maltodextrine, such as 6 % maltodextrine.

According to a presently preferred embodiment of a method for producing soy protein containing particles according to the invention the particles are produced as extruded particles in a traditional extruder using water in an amount of 21-34 % in total, such as 22-33 %, e.g. 23-32 %, such as 24-31 %, e.g. 25-30 %, such as 26-29 %, e.g. 27-28 %.

According to a presently preferred embodiment of a method for producing soy protein containing particles according to the invention the particles are produced as extruded particles in a traditional extruder using temperatures on the barrel of maximum 90 °C, such as e.g. 85 °C, for example 80 °C, such as e.g. 75 °C, for example 70 °C, such as e.g. 65 °C, for example 60 °C, such as e.g. 55 °C, for example 50 °C, such as e.g. 45 °C, for example 40 °C, such as e.g. 35 °C, for example 30 °C, such as e.g. 25 °C.

According to a presently preferred embodiment of a method for producing soy protein containing particles according to the invention the particles are produced as extruded particles in a traditional extruder using temperatures of the die of maximum 105 °C, such as e.g. 102 °C, for example 100 °C, such as e.g. 75 °C, for example 90 °C, such as e.g. 85 °C, for example 80 °C, such as e.g. 75 °C, for example 70 °C, such as e.g.

65 °C, for example 60 °C, such as e.g. 55 °C, for example 50 °C, such as e.g. 45 °C, for example 40 °C, such as e.g. 35 °C, for example 30 °C, such as e.g. 25 °C.

According to a presently preferred embodiment of a method for producing soy protein containing particles according to the invention the particles are produced as extruded particles in a traditional extruder using temperatures for drying of maximum 60 °C, such as e.g. 55 °C, for example 50 °C, such as e.g. 45 °C, for example 40 °C, such as e.g. 35 °C, for example 30 °C, such as e.g. 25 °C.

According to a presently preferred embodiment of a method for producing soy protein containing particles according to the invention the particles are produced by mixing the mixture thoroughly by adding a water solution with pregelled starch, guar gum and SSL (maximum 15 % solution) in a closed twin screw mixer and pressing the wet material through a plate with suitable holes to fit the wanted size on the beads with a temperature on the material at the outlet end of maximum 55 °C, such as e.g. 53 °C, for example 50 °C, such as e.g. 45 °C, for example 40 °C, such as e.g. 35 °C, for example 30 °C, such as e.g. 25 °C.

According to a presently preferred embodiment of a method for producing soy protein containing particles according to the invention the particles are produced by mixing the mixture thoroughly by adding a water solution with pregelled starch, guar gum and SSL (maximum 15 % solution) in a closed twin screw mixer and pressing the wet material through a plate with suitable holes to fit the wanted size on the beads using temperatures for drying of maximum 60 °C, such as e.g. 55 °C, for example 50 °C, such as e.g. 45 °C, for example 40 °C, such as e.g. 35 °C, for example 30 °C, such as e.g. 25 °C.

The soy protein containing particles according to the invention can be used as an ingredient in the production of food. Preferred food in which soy protein containing particles according to the invention may be incorporated are, baked products, such as bread, bars, mixed with ground meat e..g to be used together with pasta, as a part of meat balls, drinks such as for example juices, in soup together with meat balls or fish (might illustrate grains). For some apllications it is important that the soy protein containing particles are added just before serving, and they should preferably not be fryid or boiled in water (either necessary or wanted).

The soy blend on which soy protein containing particles according to the present invention are to be based could comprise soy constituents from any soy source available such as soy flour or any kind of a soy concentrate. In the presently most preferred embodiment of this invention said soy source is a soy protein source comprising isolated soy protein. In a preferred embodiment of the invention, said soy blend comprises soy protein in the amount of at least 45 weight percent of the total protein content. In a preferred embodiment of the invention the total protein content provides at least 15% of the total energy content of said soy blend. In a preferred embodiment of the invention the ratio of arginine to lysine of said soy protein equals to at least 1.

In a preferred embodiment of the invention the phytoestrogen compound is present in an amount of at least about 0,10 weight percent of the soy protein content of the soy blend. In a most preferred embodiment of the invention the phytoestrogen compound is selected among isoflavones. In a most preferred embodiment of the invention the isoflavones are selected from the group comprising genistein, daidzein, glycitein and equol. In a preferred embodiment of the invention some or all of the isoflavones are present in the aglycone form.

In the most preferred embodiment of the invention the soy blend further comprises soy phospholipids in an amount sufficient to provide at least 15 percent of the total energy contained in the soy blend. In a preferred embodiment of the invention the soy phospholipid source comprises at least 10 weight percent phosphatidylcholine. In a preferred embodiment of the invention the soy phospholipid source is lecithin.

In a preferred embodiment of the invention the soy blend further comprises soy dietary fibre in an amount of at least 5 weight percent. In a preferred embodiment of the invention the weight ratio of soy protein to dietary fibre is at least about 1. In a preferred embodiment of the invention the soy dietary fibre was soy cotyledon fibre.

According to the present invention the soy blend is incorporated into soy beads. Such beads can be incorporated in food products, they can for example be incorporated into dough of soy protein containing particle. According to a method of the present invention the above soy blend is incorporated into soy beads prior to being incorporated into dough of bread.

According to the present invention the soy blend is incorporated into dough of bread in the form of beads in amounts appropriate to obtain a content of soy protein corresponding to 5-12 % by weight of the dough. In a preferred embodiment of the invention the soy beads further comprise soy dietary fibre and soy phospholipids. The soy beads are incorporated into the dough in sufficient amounts to obtain a content of soy dietary fibre corresponding to 0,9-2,7 % by weight of the dough and a content of soy phospholipids corresponding to 0,07-0,83% by weight of the dough.

Hydrocolloids and proteinaceous materials all have a negative effect on bread quality. Thus, incorporating high amounts of exogenous soy protein into bread will result in reduced eating quality and reduced raising ability compared to traditional bread. This will be even worse in the occasion that the bread further comprises high amounts of an exogenous soy fibre. Furthermore bread comprising soy tends to preserve moisture for longer periods than traditional bread.

It's known that water has to be absorbed by the protein in the wheat flour in order to allow its transformation into gluten. If any absorbent material is added to a formulation of a bread it takes away water from the protein, thereby reducing gluten development with the effect of impairing the quality of the baked bread. Thus, in preferred embodiments of the invention the eating quality and raising ability will be improved by pre-hydrating the soy blend and adjusting the amount of water added to the dough. Use of these techniques allow much higher levels of soy to be incorporated into bread than previously

In a method according to the present invention the soy blend in the for of beads is preferably pre-hydrated prior to being incorporated into dough. The pre-hydration takes place by dispersing the soy blend in the form of beads in water for about 30 seconds or it can take place by simple mixing with water, with or without soaking. The purpose with mixing the soy blend with water alone is to obtain a homogenous mixture. By this pre-hydration the soy protein will be stabilised as a lot of water molecules will be forced around and in between the protein molecules and side chains thereof.

The composition of the soy blend described above is variable. In an embodiment of the invention the soy blend comprises soy protein as the only soy constituent. In a preferred embodiment of the invention the soy blend further comprises soy dietary

fibre and soy phospholipids. In this occasion the soy blend is referred to as an Abacor blend. Several variations of Abacor blend exist, thus Abacor Br, Abacor N and Abacor Sw are preferred embodiments of the invention to be explained in detail below. According to the preferred embodiments of the invention Abacor blend comprises 59 - 72% (w/w) soy protein, 12-18% (w/w) soy dietary fibre and 1-5 % (w/w) soy phospholipids.

Abacor Br comprises Soy protein isolate FXP HO 161 IP from Protein Technologies International, MO, USA comprising 87% soy protein, Fibrim 1450 from Protein Technologies International, MO, USA comprising 12% (w/w) soy protein and 80% dietary soy fibre and Epikuron 100SP/130P from Lucas Meyer GmbH & Co., Hamburg, Germany comprising either 20-24% (w/w) or 30-33% (w/w) phosphatidyl choline.

- The original Abacor Br comprises 75,7g Soy protein isolate FXP HO 161 IP, 18,9 g Fibrim 1450 and 5,4g Epikuron 100SP/130P. Thus the original Abacor Br comprises 68 % (w/w) soy protein, 15 % (w/w) soy dietary fibre and at least 1 % (w/w) phosphatidyl choline.
- The improved Abacor Br comprises 64,3g Soy protein isolate FXP HO 161 IP, 21,4 g Fibrim 1450 and 14,3 g Epikuron 130P. Thus the improved Abacor Br comprises 59 % (w/w) soy protein, 17% (w/w) soy dietary fibre and up to 4,7 % (w/w) phosphatidyl choline.

Abacor N comprises Soy protein isolate FXP HO 161 IP comprising 87 % soy protein, Fibrim 1020 from Protein Technologies International, MO, USA comprising 16 % (w/w) soy protein and 64 % dietary soy fibre and Epikuron 100SP/130P comprising either 20-24% (w/w) or 30-33% (w/w) phosphatidyl choline.

- The original Abacor N comprises 75,70g Soy protein isolate FXP HO 161 IP, 18,9 g Fibrim 1020 and 5,4g Epikuron 100SP/130P. Thus the original Abacor N comprises 69 % (w/w) soy protein, 12% (w/w) soy dietary fibre and at least 1 % (w/w) phosphatidyl choline.
- The improved Abacor N comprises 64,3g Soy protein isolate FXP HO 161 IP, 21,4 g Fibrim 1020 and 14,3 g Epikuron 130P. Thus the improved Abacor Br comprises 60 % (w/w) soy protein, 14 % (w/w) soy dietary fibre and maximum 4,7 % (w/w) phosphatidyl choline.

Abacor Sw comprises Soy protein isolate PRO FAM 940 from MultiChem Wallinco, Oslo, Norway comprising 90% soy protein, Fibrim 1020 comprising 16 % (w/w) soy

protein and 64 % dietary soy fibre and Epikuron 100SP/130P comprising either 20-24% (w/w) or 30-33% (w/w) phosphatidyl choline.

- The original Abacor Sw comprises 75,7 g Soy protein isolate PRO FAM 940, 18,9 g Fibrim 1020 and 5,4 g Epikuron 100SP/130P. Thus the original Abacor Br comprises 71 % (w/w) soy protein 12 % (w/w) soy dietary fibre and at least 1% (w/w) phosphatidyl choline
- The improved Abacor Sw comprises 64,3 g Soy protein isolate PRO FAM, 21,4g Fibrim 1020 and 14,3 g Epikuron 130P. Thus the improved Abacor Br comprises 61 % (w/w) soy protein, 14 % (w/w) soy dietary fibre and up to 4,7 % (w/w) phosphatidyl choline

As mentioned above incorporating soy blend into dough will influence the dough moisture. Compensation for this is achieved by pre-hydrating the soy-blend in form of beads or simply by incorporating extra water into dough. As it appears from the above water is the preferred liquid for this use, though any liquid chosen from the group consisting of water, milk and juice could be used for pre-hydrating the soy blend. In the preferred embodiments of the invention the amount of water used for the pre-hydration was between 5 and 17 grams of water for each gram of soy fibre being incorporated into the dough.

In a preferred embodiment of the invention the soy blend is incorporated into small beads with a high bulk density. The beads are crunchy and may be of any shape, e.g. nuggets, flakes or the like and they might be achieved in several ways. Methods of forming beads comprise:

- extrusion cooking with starch from cereal or other vegetable sources
- extrusion with pregelatinised starch and drying
- extrusion with thermo-labile gelling agents and further thermal treatment with microwaves or hot air
- extrusion with cold setting chemical gelling agent

The water absorbing properties of the soy beads are reduced significantly compared to the soy blend. If dry beads are employed in a dough, their water absorption will therefore, be sufficient to reduce final soy protein containing particle volumes. This can be overcome by adding extra water in an amount depending on the rate and extent of water uptake by the soy beads. In an embodiment of the invention the extra water is

simply added to the dough together with the remainder water. In another embodiment of the invention the water is used for pre-hydrating the beads prior to incorporating them into dough. When pre-hydrated, the beads are dispersed in water for 7 minutes before use. From an embodiment of the invention it appears that use of dry beads give soy protein containing particle with larger volume, more open crumb and more acceptable flavour than when using pre-hydrated beads.

In order to obtain a good eating quality of the resulting soy protein containing particle it is, however, not critical whether the beads were pre-hydrated or not, the moisture of the final dough is of much greater importance. When an appropriate amount of extra water is added to dough high levels of beads can be incorporated into dough which can then be baked into a high quality soy protein containing particle. As the soy protein and fibres are trapped in the small particles, they cannot escape into the dough in sufficient concentration to absorb water. In this way their interference with the development of gluten structure is avoided.

In a preferred embodiment of the invention the beads comprise a blend comprising soy protein, soy dietary fibre and soy phospolipids. As such a blend is an Abacor blend the beads produced hereof are referred to as Abacor beads. In the most preferred embodiments of the invention Abacor beads comprise 50,9% (w/w) soy protein, 9,9% (w/w) soy dietary fibre and between 0,80% (w/w) and 3,54% (w/w) phosphatidyl choline.

In a preferred embodiment of the invention the beads to be incorporated into dough further comprise starch such as wheat starch, rice starch, potato starch and maize starch in addition to a sugar compound such as Maltodextrine (DE 15). When comprising such a sugar compound it's necessary carefully to control the content of reducing sugars contributing to Maillard reactions thereby causing a burnt crust appearance. In one most preferred embodiment of the invention the Abacor beads consist of 75% (w/w) Abacor blend, 21% (w/w) Wheat starch and 4% (w/w) Maltodextrine (DE 15).

As mentioned above incorporating soy beads into dough will influence the dough moisture. Compensation for this is achieved by pre-hydrating the soy beads or simply by incorporating extra water into dough. As it appears from the above, water is the preferred liquid for this use, though any liquid chosen from the group consisting of

water, milk and juice could be used for pre-hydrating the soy beads. In the preferred embodiments of the invention the amount of water used for the pre-hydration was between 5 and 17 grams of water for each gram of soy fibre being incorporated into the dough.

Another parameter influencing the moisture is the flour to be incorporated into the dough. According to the present invention any kind of common flour for making soy protein containing particle such as wheat flour, whole meal flour, gluten, rye flour, oat flour and oat flakes can be incorporated into the dough. In order to obtain a proper soy protein containing particle quality it's important to adjust the dough moisture after the kind of flour and the flour quality. Further, in some occasions the soy protein containing particle quality may be improved if e.g. oat flakes and whole meal flour is soaked in water prior to being incorporated into dough.

Another parameter influencing the moisture is the flour to be incorporated into the dough. According to the present invention any kind of common flour for making bread such as wheat flour, whole meal flour, gluten, rye flour, oat flour and oat flakes can be incorporated into the dough. In order to obtain a proper bread quality it's important to adjust the dough moisture after the kind of flour and the flour quality. Further, in some occasions the bread quality may be improved if e.g. oat flakes and whole meal flour is soaked in water prior to being incorporated into dough.

If a dough comprising beads is made by the sponge and dough method a sponge of flour, yeast and water is added together with the remainder ingredients. The sponge has previously rested for 4 or 16 hours. If the dough does not comprise a sponge, the flour is blended with the enzymatic preparation for 30 minutes prior to mixing with the remainder ingredients.

In preferred embodiments of the invention the English flour "Prarie Gold" and the Norwegian flour "Spesialmel" from "Norgesmøllerne DA", Bergen, Norway are used. The water absorption is higher for the English flour than for the Norwegian flour and there is compensated for this by adding extra water to the dough comprising the English flour. The development time for those two brands of wheat flour is different thus indicating differences in flour quality. Another parameter indicating differences in flour quality is the gluten content and the protein level of the flour e.g. the protein levels differ among the brands Strong Bread Making Flour, Dark Northern Springs flour

and Nimrod flour. Exogenous baking additives like gluten, emulsifiers and enzyme additives can compensate for differences in flour quality.

As mentioned above the bread quality will improve significantly when incorporating an appropriate enzyme preparation into the dough. Thus, according to the preferred embodiments of the invention, exogenous enzyme is incorporated in amounts of 0 or 0,17-3,0% by weight of the fibre content of the dough. Addition of an amymolytic enzyme preparation will increase the volume and induce the formation of a nicer crust and a better breadcrumb structure of the bread. In an embodiment of the invention Xylanase and Fungal Alpha Amylase was shown to improve the volume of the bread. In another embodiment of the invention the enzyme preparation has transglutaminase and hemicellulase activities in addition to the amymolytic enzyme activity. This enzyme preparation is obtained from specific cultures of Aspergillus oryzae and it is available as Veron® CLX from Röhm Enzyme Gmbh.

Enzyme products comprising transglutaminase provide an improved bread quality by stabilising the gluten structure. Transglutaminase creates new bonds between amino acids as it links peptide chains and stabilises the protein structure by catalysing an acyl transfer reaction between the amino acids lysine and glutamine. Gluten is, together with starch and hemicelluloses, responsible for the properties of the dough and influences the entire baking process up to the finished bread. Veron® CLX therefore crosslinks the gluten and improves the consistency of the dough. By using Veron® CLX high baking volume, dry and fluffy dough, good dough stability, good proving stability and good gas retention capacity is obtained. Furthermore, Veron® CLX provides an improved bread quality, a nicer bread crust and a good breadcrumb structure.

The emulsifier usually contained in baking additives are substances promoting the homogeneity of the dough through their surfactant properties. By using an emulsifier the pores in the breadcrumb will render more dense whereby the bread quality will improve. Veron® CLX provides these properties thus reducing the need of emulsifiers. In preferred embodiments of the invention emulsifiers such as Sodium Stearoyl Lactylate (SSL) from Paalgard Industry A/S, Denmark and DATA are incorporated into the dough in amounts corresponding to 9,5 –19 % by weight of the fibre content of the dough.

It appears from the above, that gluten is essential for the bread quality. Accordingly, incorporation of exogenous gluten is essential for good baking results. Thus, the preferred embodiments of the invention comprise incorporation of exogenous gluten, such as Protinax from SFK Norge AS, Skytta, Norway, into dough in amounts corresponding to 0 or 100-530 % by weight of the fibre content of the dough. Thereby both the dough extensibility and the gas retention capability are enhanced.

In addition to the baking additives mentioned above, fat can be added in order to improve the volume of the bread. In an embodiment of the invention fat is included at a level of 2% corresponding to the amount currently used in normal white bread.

Any kind of yeast could be used for the fermentation. According to a preferred embodiment of the invention instant dry yeast such as Instant dry yeast for lean doughs from Lesaffre, France and Femipan from Gist-brocades, Netherlands is used. There appears to be no difference in the fermentation rates measured when using these two kinds of instant dry yeast.

According to the invention it's an option to incorporate shortening into dough, though a preferred embodiment of the invention does not comprise use of shortening for making wholemeal bread as it appears to make the breadcrumb divide just below the crust.

In one preferred embodiment of the invention the dough is mixed by use of a commercial dough mixer such as Diosna SP 40 from (Diosna, Dierks & Söhne Gmbh, Osnabruk, Germany). If the soy blend is pre-hydrated at the point of addition the remainder ingredients are mixed with 2 minutes at 100 rpm and 3,5 minutes at 200 rpm. A final mixing programme whereby all the ingredients are mixed to dough consists of 2 minutes at 100 rpm and 0,5 minutes at 200 rpm. If the soy preparation is dry at the point of addition it is sieved together with the flour and the mixing programme is reduced to consist of the final mixing. After finalising the mixing procedure the dough temperature appears to be 25-27°C, in the event that it is measured.

In another embodiment of the invention the dough is mixed by use of a spiral mixer such as a 32kg Spiral Mixer. All the ingredients including the pre-hydrated or dry beads are mixed with 2 minutes at 100 rpm and 12 minutes at 200 rpm.

In another preferred embodiment of the invention the dough is mixed using atmospheric mixing or atmospheric/vacuum mixing such as Tweedy 35. All the ingredients including the pre-hydrated or dry soy preparation are placed in a CBP unit and dough is mixed for the time required for about 11 watts per kilo to be achieved. If atmospheric/vacuum mixing is used a 15" vacuum is pulled at 48 watt hours.

After mixing, the dough rests for up to 30 minutes. From an embodiment of the invention it appears that resting makes the crust of white flour bread more open with pores that looks like wounds and that no resting gives the highest bread volume. Now the dough is divided into pieces by hand or by use of a machine such as a single stage vacuum divider from Glimek AB, Glimåkra, Sweden. In preferred embodiments of the invention the sizes of the dough pieces are between 460g and 930g. The dough pieces are moulded by hand or by using a machine such as a conical rounder from Glimek AB.

In an embodiment of the invention an intermediate proofing as e.g. 5-10 minutes is applied. In an embodiment of the invention the intermediate prove takes place at a conveyor belt before sheeting, curling and the final mould. In another embodiment of the invention the intermediate proofing takes place in an intermediate proof cabinet.

The dough is finally moulded by hand or by using a machine such as a drum and roller sheeter from Glimek AB or a CCFRA moulder from Sorensen Moulder. Alternatively it is put into rye baskets dusted with rye flour or pans. According to the invention it appears that use of mechanical sheeting gives a smoother bread crust than sheeting the dough by hand. When handling the dough by machine it's essential that the moisture is appropriate. Thus, if the dough is too sticky there might appear a problem with the dough weight as the dough sticks to the rollers in the mechanical roller sheeter. In preferred embodiments of the invention the dough moisture appears to be 43 - 45% in the event it's determined.

The dough proves in a proofing cabinet. In one embodiment of the invention the dough proves for 35 minutes with the cabinet set at 37°C with 78% RH. In another embodiment of the invention the dough proves to touch with the cabinet set at 43°C with 80% R/H.

In one embodiment of the invention the dough proves in rye baskets and the dough is turned upside down onto baking trays. The dough pieces are then placed on steel trays. In another embodiment of the invention the dough pieces are placed in greased 400g tins and proved to a height of 10 cm.

After proofing, the loaves are baked. Any convenient baking time and temperature can be used. In a preferred embodiment of the invention the baking time is between 20 and 35 minutes and the baking temperature is between 220 and 270°C. In an embodiment of the invention steam is added during the first 20-30 seconds of baking or after half the baking time.

From a subjective quality test performed on 19-hour-old bread prepared according to preferred embodiments of the invention and stored at room temperature in plastic bags it appears that bread made according to the present invention has a good eating quality. The test panel consisted of 2 skilled bakers and 2 research scientists, and the results are listed below:

Sensory characteristic	White bread	Whole meal flour bread
Soy flacour	3	4
Bitter flavour	3	4
Powder feeling, clinginess	3	2, the bread piece increase in volume in the mouth
Rancidity	4	4
Smell, odour, wet hay	3	2
Crumb consistency, wetness	2	3

1 is poor quality or the sensory characteristic is very dominating

4 is very good quality or the sensory characteristic is not tasted

The soy protein for use in a soy protein containing particle according to the present invention can be provided by isolated soy protein, soy protein concentrate, soy flour or the like or any combination thereof. Isolated soy protein is preferred. Processed Isolated soy protein is particularly preferred.

Isolated soy protein is the major proteinacious fraction of soybeans. It is prepared from high quality, dehulled, defatted soybeans by removing a preponderance of the non-protein components resulting in an isolated soy protein fraction which in the present context shall contain at least 90 percent protein (N x 6.25) on a moisture free basis.

The preparation takes place through a series of steps in which the soybean protein portion is separated from the rest of the soybean. The removal of carbohydrate results in a product, which is essentially bland in flavor and therefore particularly useful in a soy protein containing particle for humans.

Soy protein concentrates are made by removing most of the oil and water-soluble non-protein constituents from defatted and dehulled soybeans. In the present context a soy protein concentrate shall preferably contain at least 65 percent protein on a moisture-free basis.

The soy protein can also be provided by soy flour, which can be full-fat or defatted soy flour. Full-fat soy flour comes from whole, dehulled soybeans that have been ground into a fine powder and, as the name implies, still contains the fat naturally found in soybeans. Defatted soy flour comes from whole, dehulled, defatted soybeans that have been ground into a fine powder. Soy flour is approximately 50 percent soy protein on a dry weight basis in the present context.

The soy protein used in a soy protein containing particle according to the present invention should preferably supply all the essential amino acids in the amounts required for humans. Preferably, the soy protein should also meet or exceed the essential amino acid requirement pattern for children and adults as established by the Food and Agricultural Organization, World Health Organization and United Nations University (FAO/WHO, UNU). Furthermore, the preferred soy protein should be comparable in digestibility to milk, meat, fish, and egg protein. Finally, the preferred soy protein shall be effective in maintaining nitrogen balance when consumed at the recommended protein intake level.

Researcher have shown that specific amino acids may to some extent effect serum lipid levels and potentially alleviate cardiovascular diseases. Animal studies have indicated that the amino acid lysine increases serum cholesterol levels, while arginine counteracts this effect (Kurowska et al., J. Nutr. 124, 364-370 (1994) and Sanchez et al., Med. Hypotheses 35, 324-329 (1991). This observation appears to be in correspondence with the well established influence of NO on vasodilation, since arginine may potentially be converted to citrullin and NO by NO-synthetase. Thus according to a presently preferred hyphothesis soy protein having a high arginine to lysine ratio effects serum lipid levels and alleviates symptoms of cardiovascular

diseases to a greater extent than soy protein having a lower or normal arginine to lysine ratio. Consequently, isolated, potentially processed, soy protein having a high arginine to lysine ratio is a particularly preferred soy protein source in a soy protein containing particle according to the present invention. Preferably the soy protein of the soy protein source in a soy protein containing particle according to the present invention should have an arginine to lysine ratio of at least about 1.0, such as at least about 1.1, for example at least about 1.2, such as at least about 1.3, for example at least about 1.4, such as at least about 1.5, for example at least about 1.6, such as at least about 1.7, for example at least about 1.8, such as at least about 1.9, for example more than about 2, such as at least about 2.1, for example at least about 2.2, such as at least about 2.5, for example at least about 2.75, such as at least about 3, for example more than about 3.3, such as at least about 3.6, for example at least about 4, such as at least about 4.5, for example at least about 5, such as at least about 6, for example at least about 7, such as at least about 8, for example at least about 9, such as at least about 10, for example at least about 11, such as at least about 12, for example at least about 13, such as at least about 14.

Preferred isolated soy protein products meeting some or all of the foregoing requirements are supplied by Protein Technologies International, Inc. under the brand name SUPRO®. SUPRO® isolated soy proteins are supplied in many different qualities and SUPRO® XT 12C is one particularly preferred quality. The currently most preferred quality is termed SUPRO® FXP-HO159.

The soy protein is preferably the main protein source in a soy protein containing particle according to the present invention. However, parts of the protein source may be provided by other proteins such as e.g. skimmed milk, preferably as a powder, and other vegetable or animal proteins including diary proteins.

In a preferred embodiment of the invention the soy protein is provided by isolated soy protein

Phytoestrogen compounds according to the present invention are defined as naturally occurring plant substances, said substances being either structurally or functionally similar to 17□-estradiol or generating estrogenic effects. Phytoestrogens consist of a number of classes including isoflavones, coumestans, lignans and resorcylic acid lactones. Examples of isoflavones according to the present invention are genistein,

daidzein, equol, glycitein, biochanin A, formononetin, and O-desmethylangolesin. The phytoestrogen compounds of a soy protein containing particle according to the present invention are preferably isoflavones, more preferably genistein, daidzein, glycitein and/or equol, yet more preferably genistein and/or daidzein, and even more preferably genistein. A preferred soy protein containing particle according to the present invention may accordingly comprise a single isoflavone, such as genistein, daidzein, glycitein or equol, or it may comprise at least one isoflavone selected from the group comprising at least genistein, daidzein, glycitein and equol. When present in the plant the isoflavones are mainly in a glucoside form, i.e. attached to a sugar molecule. This glucoside form can be deconjugated to yield a so-called aglycone form, which is the biologically active species. A soy protein containing particle according to the present invention may comprise isoflavones in glucoside and/or aglycone forms regardless of whether the deconjugation to the aglycone form has taken place biologically, in vitro or by any other means whereby the isoflavones are included in a soy protein containing particle according to the present invention or if the aglycone forms are the native form of the isoflavones.

The phytoestrogen compound is preferably present in an amount of at least about 0.10 weight percent of the soy protein content. More preferably the phytoestrogen compound is present in an amount of at least 0.10 weight percent of the soy protein content, such as at least about 0.11 weight percent, for example at least about 0.12 weight percent, such as at least about 0.14 weight percent, for example at least about 0.16 weight percent, such as at least about 0.18 weight percent, for example at least about 0.20 weight percent, such as at least about 0.22 weight percent, for example at least about 0.24 weight percent, such as at least about 0.25 weight percent, for example more than about 0.25 weight percent, such as at least about 0.26 weight percent, for example at least about 0.28 weight percent, such as at least about 0.30 weight percent, for example at least about 0.32 weight percent, such as at least about 0.33 weight percent, for example more than about 0.33 weight percent, such as at least about 0.35 weight percent, for example at least about 0.40 weight percent, such as at least about 0.45 weight percent, for example at least about 0.50 weight percent, such as at least about 0.55 weight percent, for example at least about 0.60 weight percent, such as at least about 0.65 weight percent, for example at least about 0.70 weight percent, such as at least about 0.75 weight percent, for example at least about 0.80 weight percent, such as at least about 0.85 weight percent, for example at least

about 0.90 weight percent, such as at least about 1.0 weight percent of the soy protein content, and preferably less than 2.50 weight percent of the soy protein content.

In the past, the downstream processing techniques used in the preparation of soy proteins have included steps that removed and/or destroyed isoflavones. Methods are available today, which provide soy protein products with high, fixed levels of naturally occurring isoflavones. The isoflavones according to the present invention in glucoside and/or aglycone forms can be included in a soy protein containing particle according to the present invention as part of such soy protein products and/or by themselves and/or as part of any other soy protein containing particle comprising isoflavones.

According to a preferred embodiment of the present invention the soy protein used in a process for the preparation of a soy protein containing particle according to the present invention retain the ability to lower blood cholesterol levels upon ingestion, characterised by having more than a further specified minimum content of intact 7S (α + α' + β) and/or 11S subunits (A + B).

Without wishing to be bound by theory it is believed that ingestion of soy proteins with minimum content of intact 7S (α + α' + β) and/or 11S subunits (A + B) facilitate the formation of breakdown products in the digestive tract, in the form of peptides which elicit an effect in the form of cholesterol lowering.

The present invention also provides the use of soy protein in a soy protein containing particle according to the present invention, which retains the ability to lower blood cholesterol levels upon ingestion, characterised by minimum content of intact 7S (α + α' + β) and/or 11S subunits (A + B), and also provides for the use of such a soy protein containing particle in which the soy protein retains the ability to lower blood cholesterol levels upon ingestion to obtain a health benefit.

In one aspect the present invention provides soy protein containing particle comprising soy protein, which retains the ability to lower blood cholesterol levels upon ingestion, characterised by a minimum content of intact 7S (α + α' + β) and/or 11S subunits (A + B). The soy protein of such a soy protein containing particle more specifically are believed facilitate the formation of peptides which has a cholesterol lowering effect.

In another aspect, the present invention provides a method for manufacturing a soy protein containing particle product, wherein the soy protein retains the ability to lower blood cholesterol levels upon ingestion and characterised by a minimum content of intact 7S (α + α' + β) and/or 11S subunits (A + B)

The amount of intact 7S subunits (α + α' + β) and 11S subunits (A + B) in the soy protein used in the preparation of a soy protein containing particle according to the invention preferably constitute more than 5 % of the total soy protein content, such as more than 10 %, for example more than 15 %, , such as more than 20 %, for example more than 25 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 51 %, such as more than 52 %, for example more than 53 %, such as more than 54 %, for example more than 55 %, such as more than 56 %, for example more than 57 %, such as more than 58 %, for example more than 59 %, such as more than 60 %, for example more than 61 %, such as more than 62 %, for example more than 63 %, such as more than 64 %, for example more than 65 %, such as more than 66 %, for example more than 67 %, such as more than 68 %, for example more than 69 %, such as more than 70 %, for example more than 71 %, such as more than 72 %, for example more than 73 %, such as more than 74 %, for example more than 75 %, such as more than 77 %, for example more than 79 %, such as more than 81 %, for example more than 83 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

The amount of intact 7S subunits (α + α' + β) in the soy protein used in the preparation of a soy protein containing particle according to the invention preferably constitute more than 1 % of the total soy protein content, such as more than 2 %, for example more than 3 %, such asmore than 4 %, for example more than 5 %, such as more than 6 %, for example more than 7 %, such as more than 8 %, for example more than 9 %, such as more than 10 %, for example more than 11 %, such as more than 12 %, for example more than 13 %, such as more than 14 %, for example more than 15 %, such as more than 16 %, for example more than 17 %, such as more than 18 %, for

example more than 19 %, such as more than 20 %, for example more than 21 %, such as more than 22 %, for example more than 23 %, such as more than 24 %, for example more than 25 %, such as more than 26 %, for example more than 27 %, such as more than 28 %, for example more than 29 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 55 %, such as more than 60 %, for example more than 65 %, such as more than 70 %, for example more than 75 %, such as more than 80 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

The amount of intact 7S subunit α in the soy protein used in the preparation of a soy protein containing particle according to the invention preferably constitute more than 1 % of the total soy protein content, such as more than 2 %, for example more than 3 %, such asmore than 4 %, for example more than 5 %, such as more than 6 %, for example more than 7 %, such as more than 8 %, for example more than 9 %, such as more than 10 %, for example more than 11 %, such as more than 12 %, for example more than 13 %, such as more than 14 %, for example more than 15 %, such as more than 16 %, for example more than 17 %, such as more than 18 %, for example more than 19 %, such as more than 20 %, for example more than 21 %, such as more than 22 %, for example more than 23 %, such as more than 24 %, for example more than 25 %, such as more than 26 %, for example more than 27 %, such as more than 28 %, for example more than 29 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 55 %, such as more than 60 %, for example more than 65 %, such as more than 70 %, for example more than 75 %, such

as more than 80 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

The amount of intact 7S subunit α' in the soy protein used in the preparation of a soy protein containing particle according to the invention preferably constitute more than 1 % of the total soy protein content, such as more than 2 %, for example more than 3 %, such asmore than 4 %, for example more than 5 %, such as more than 6 %, for example more than 7 %, such as more than 8 %, for example more than 9 %, such as more than 10 %, for example more than 11 %, such as more than 12 %, for example more than 13 %, such as more than 14 %, for example more than 15 %, such as more than 16 %, for example more than 17 %, such as more than 18 %, for example more than 19 %, such as more than 20 %, for example more than 21 %, such as more than 22 %, for example more than 23 %, such as more than 24 %, for example more than 25 %, such as more than 26 %, for example more than 27 %, such as more than 28 %, for example more than 29 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 55 %, such as more than 60 %, for example more than 65 %, such as more than 70 %, for example more than 75 %, such as more than 80 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

According to a particularly preferred embodiment of the present invention the soy protein used in the preparation of a soy protein containing particle according to the invention also contain phytoestrogens, such as isoflavons. The phytoestrogen compound is preferably present in an amount of at least about 0.12 weight percent of the soy protein content, such as at least about 0.14 weight percent, for example at least about 0.16 weight percent, such as at least about 0.18 weight percent, for example at least about 0.20 weight percent, such as at least about 0.22 weight percent, for example at least about 0.24 weight percent, such as at least about 0.25 weight percent, for example more than about 0.25 weight percent, such as at least about 0.26 weight percent, for example at least about 0.28 weight percent, such as at

least about 0.30 weight percent, for example at least about 0.32 weight percent, such as at least about 0.33 weight percent, for example more than about 0.33 weight percent, such as at least about 0.35 weight percent, for example at least about 0.40 weight percent, such as at least about 0.45 weight percent, for example at least about 0.50 weight percent, such as at least about 0.55 weight percent, for example at least about 0.60 weight percent, such as at least about 0.65 weight percent, for example at least about 0.70 weight percent, such as at least about 0.75 weight percent, for example at least about 0.80 weight percent, such as at least about 0.85 weight percent, for example at least about 0.90 weight percent, such as at least about 1.0 weight percent of the soy protein content, and preferably less than 2.50 weight percent of the soy protein content.

In soy protein used in the preparation of a soy protein containing particle according to the invention with an amount of isoflavones of at least 0.16 weight % of the soy protein, the amount of intact 7S subunits (α + α' + β) and 11S subunits (A + B) preferably constitute more 5 % of the total soy protein content, such as more than 10 %, for example more than 15 %, , such as more than 20 %, for example more than 25 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 51 %, such as more than 52 %, for example more than 53 %, such as more than 54 %, for example more than 55 %, such as more than 56 %, for example more than 57 %, such as more than 58 %, for example more than 59 %, such as more than 60 %, for example more than 61 %, such as more than 62 %, for example more than 63 %, such as more than 64 %, for example more than 65 %, such as more than 66 %, for example more than 67 %, such as more than 68 %, for example more than 69 %, such as more than 70 %, for example more than 71 %, such as more than 72 %, for example more than 73 %, such as more than 74 %, for example more than 75 %, such as more than 77 %, for example more than 79 %, such as more than 81 %, for example more than 83 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

In soy protein used in the preparation of a soy protein containing particle according to the invention with an amount of isoflavones of at least 0.16 %, the amount of intact 7S subunits (α + α' + β) preferably constitute more than than 3 %, such as more than 4 %, for example more than 5 %, such as more than 6 %, for example more than 7 %, such as more than 8 %, for example more than 9 %, such as more than 10 %, for example more than 11 %, such as more than 12 %, for example more than 13 %, such as more than 14 %, for example more than 15 %, such as more than 16 %, for example more than 17 %, such as more than 18 %, for example more than 19 %, such as more than 20 %, for example more than 21 %, such as more than 22 %, for example more than 23 %, such as more than 24 %, for example more than 25 %, such as more than 26 %, for example more than 27 %, such as more than 28 %, for example more than 29 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 55 %, such as more than 60 %, for example more than 65 %, such as more than 70 %, for example more than 75 %, such as more than 80 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

In soy protein used in the preparation of a soy protein containing particle according to the invention with an amount of isoflavones of at least 0.16 % of the soy protein, the amount of intact 7S subunit α preferably constitute more than 1 % of the total soy protein content, such as more than 2 %, for example more than 3 %, such asmore than 4 %, for example more than 5 %, such as more than 6 %, for example more than 7 %, such as more than 8 %, for example more than 9 %, such as more than 10 %, for example more than 11 %, such as more than 12 %, for example more than 13 %, such as more than 14 %, for example more than 15 %, such as more than 16 %, for example more than 17 %, such as more than 18 %, for example more than 19 %, such as more than 20 %, for example more than 21 %, such as more than 22 %, for example more than 23 %, such as more than 24 %, for example more than 25 %, such as more than 26 %, for example more than 27 %, such as more than 28 %, for example more than 29 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for

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In soy protein used in the preparation of a soy protein containing particle according to the invention with an amount of isoflavones of at least 0.16 % of the soy protein, the amount of intact 7S subunit α' preferably constitute more than 1 % of the total soy protein content, such as more than 2 %, for example more than 3 %, such asmore than 4 %, for example more than 5 %, such as more than 6 %, for example more than 7 %, such as more than 8 %, for example more than 9 %, such as more than 10 %, for example more than 11 %, such as more than 12 %, for example more than 13 %, such as more than 14 %, for example more than 15 %, such as more than 16 %, for example more than 17 %, such as more than 18 %, for example more than 19 %, such as more than 20 %, for example more than 21 %, such as more than 22 %, for example more than 23 %, such as more than 24 %, for example more than 25 %, such as more than 26 %, for example more than 27 %, such as more than 28 %, for example more than 29 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 55 %, such as more than 60 %, for example more than 65 %, such as more than 70 %, for example more than 75 %, such as more than 80 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

Optionally a soy protein product used in the preparation of a soy protein containing particle according to the invention may have the trypsin inhibitors partly or fully

destroyed or removed. The amount of ACTIVE trypsin inhibitor in a soy protein product used in the preparation of a soy protein containing particle according to the invention may preferably be less than 50% of the amount in the original soy bean, such as less than 40%, for example less than 30%, such as less than 25%, for example less than 20%, such as less than 15%, for example less than 10%, such as less than 5 %, for example less than 1%.

The amount of intact 7S subunits (α + α' + β) and 11S subunits (A + B) in the soy protein in a soy protein containing particle according to the invention preferably constitute more than 5 % of the total soy protein content, such as more than 10 %, for example more than 15 %, , such as more than 20 %, for example more than 25 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 51 %, such as more than 52 %, for example more than 53 %, such as more than 54 %, for example more than 55 %, such as more than 56 %, for example more than 57 %, such as more than 58 %, for example more than 59 %, such as more than 60 %, for example more than 61 %, such as more than 62 %, for example more than 63 %, such as more than 64 %, for example more than 65 %, such as more than 66 %, for example more than 67 %, such as more than 68 %, for example more than 69 %, such as more than 70 %, for example more than 71 %, such as more than 72 %, for example more than 73 %, such as more than 74 %, for example more than 75 %, such as more than 77 %, for example more than 79 %, such as more than 81 %, for example more than 83 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

The amount of intact 7S subunits (α + α' + β) in the soy protein in a soy protein containing particle according to the invention preferably constitute more than 1 % of the total soy protein content, such as more than 2 %, for example more than 3 %, such asmore than 4 %, for example more than 5 %, such as more than 6 %, for example more than 7 %, such as more than 8 %, for example more than 9 %, such as more than 10 %, for example more than 11 %, such as more than 12 %, for example more

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The amount of intact 7S subunit α in the soy protein in a soy protein containing particle according to the invention preferably constitute more than 1 % of the total soy protein content, such as more than 2 %, for example more than 3 %, such asmore than 4 %, for example more than 5 %, such as more than 6 %, for example more than 7 %, such as more than 8 %, for example more than 9 %, such as more than 10 %, for example more than 11 %, such as more than 12 %, for example more than 13 %, such as more than 14 %, for example more than 15 %, such as more than 16 %, for example more than 17 %, such as more than 18 %, for example more than 19 %, such as more than 20 %, for example more than 21 %, such as more than 22 %, for example more than 23 %, such as more than 24 %, for example more than 25 %, such as more than 26 %, for example more than 27 %, such as more than 28 %, for example more than 29 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 55 %, such as more than 60 %, for example more than 65 %, such

as more than 70 %, for example more than 75 %, such as more than 80 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

The amount of intact 7S subunit α' in the soy protein in a soy protein containing particle according to the invention preferably constitute more than 1 % of the total soy protein content, such as more than 2 %, for example more than 3 %, such asmore than 4 %, for example more than 5 %, such as more than 6 %, for example more than 7 %, such as more than 8 %, for example more than 9 %, such as more than 10 %, for example more than 11 %, such as more than 12 %, for example more than 13 %, such as more than 14 %, for example more than 15 %, such as more than 16 %, for example more than 17 %, such as more than 18 %, for example more than 19 %, such as more than 20 %, for example more than 21 %, such as more than 22 %, for example more than 23 %, such as more than 24 %, for example more than 25 %, such as more than 26 %, for example more than 27 %, such as more than 28 %, for example more than 29 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 55 %, such as more than 60 %, for example more than 65 %, such as more than 70 %, for example more than 75 %, such as more than 80 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

According to a particularly preferred embodiment of the present invention the soy protein in a soy protein containing particle according to the invention also contain phytoestrogens, such as isoflavons. The phytoestrogen compound is preferably present in an amount of at least about 0.12 weight percent of the soy protein content, such as at least about 0.14 weight percent, for example at least about 0.16 weight percent, such as at least about 0.18 weight percent, for example at least about 0.20 weight percent, such as at least about 0.22 weight percent, for example at least about 0.24 weight percent, such as at least about 0.25 weight percent, for example more than about 0.25 weight percent, such as at least about 0.26 weight percent, for example at least about 0.28 weight percent, such as at least about 0.30 weight

percent, for example at least about 0.32 weight percent, such as at least about 0.33 weight percent, for example more than about 0.33 weight percent, such as at least about 0.35 weight percent, for example at least about 0.40 weight percent, such as at least about 0.45 weight percent, for example at least about 0.50 weight percent, such as at least about 0.55 weight percent, for example at least about 0.60 weight percent, such as at least about 0.65 weight percent, for example at least about 0.70 weight percent, such as at least about 0.75 weight percent, for example at least about 0.80 weight percent, such as at least about 0.85 weight percent, for example at least about 0.90 weight percent, such as at least about 1.0 weight percent of the soy protein content, and preferably less than 2.50 weight percent of the soy protein content.

In soy protein in a soy protein containing particle according to the invention with an amount of isoflavones of at least 0.16 weight % of the soy protein, the amount of intact 7S subunits (α + α' + β) and 11S subunits (A + B) preferably constitute more 5 % of the total soy protein content, such as more than 10 %, for example more than 15 %, , such as more than 20 %, for example more than 25 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 51 %, such as more than 52 %, for example more than 53 %, such as more than 54 %, for example more than 55 %, such as more than 56 %, for example more than 57 %, such as more than 58 %, for example more than 59 %, such as more than 60 %, for example more than 61 %, such as more than 62 %, for example more than 63 %, such as more than 64 %, for example more than 65 %, such as more than 66 %, for example more than 67 %, such as more than 68 %, for example more than 69 %, such as more than 70 %, for example more than 71 %, such as more than 72 %, for example more than 73 %, such as more than 74 %, for example more than 75 %, such as more than 77 %, for example more than 79 %, such as more than 81 %, for example more than 83 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

In soy protein in a soy protein containing particle according to the invention with an amount of isoflavones of at least 0.16 %, the amount of intact 7S subunits (α + α' + β) preferably constitute more than than 3 %, such as more than 4 %, for example more than 5 %, such as more than 6 %, for example more than 7 %, such as more than 8 %, for example more than 9 %, such as more than 10 %, for example more than 11 %, such as more than 12 %, for example more than 13 %, such as more than 14 %, for example more than 15 %, such as more than 16 %, for example more than 17 %, such as more than 18 %, for example more than 19 %, such as more than 20 %, for example more than 21 %, such as more than 22 %, for example more than 23 %, such as more than 24 %, for example more than 25 %, such as more than 26 %, for example more than 27 %, such as more than 28 %, for example more than 29 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 55 %, such as more than 60 %, for example more than 65 %, such as more than 70 %, for example more than 75 %, such as more than 80 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

In soy protein in a soy protein containing particle according to the invention with an amount of isoflavones of at least 0.16 % of the soy protein, the amount of intact 7S subunit α preferably constitute more than 1 % of the total soy protein content, such as more than 2 %, for example more than 3 %, such asmore than 4 %, for example more than 5 %, such as more than 6 %, for example more than 7 %, such as more than 8 %, for example more than 9 %, such as more than 10 %, for example more than 11 %, such as more than 12 %, for example more than 13 %, such as more than 14 %, for example more than 15 %, such as more than 16 %, for example more than 17 %, such as more than 18 %, for example more than 19 %, such as more than 20 %, for example more than 21 %, such as more than 22 %, for example more than 23 %, such as more than 24 %, for example more than 25 %, such as more than 26 %, for example more than 27 %, such as more than 28 %, for example more than 29 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such

as more than 36 %, for exampie more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 55 %, such as more than 60 %, for example more than 65 %, such as more than 70 %, for example more than 75 %, such as more than 80 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

In soy protein in a soy protein containing particle according to the invention with an amount of isoflavones of at least 0.16 % of the soy protein, the amount of intact 7S subunit α' preferably constitute more than 1 % of the total soy protein content, such as more than 2 %, for example more than 3 %, such asmore than 4 %, for example more than 5 %, such as more than 6 %, for example more than 7 %, such as more than 8 %, for example more than 9 %, such as more than 10 %, for example more than 11 %, such as more than 12 %, for example more than 13 %, such as more than 14 %, for example more than 15 %, such as more than 16 %, for example more than 17 %, such as more than 18 %, for example more than 19 %, such as more than 20 %, for example more than 21 %, such as more than 22 %, for example more than 23 %, such as more than 24 %, for example more than 25 %, such as more than 26 %, for example more than 27 %, such as more than 28 %, for example more than 29 %, such as more than 30 %, for example more than 31 %, such as more than 32 %, for example more than 33 %, such as more than 34 %, for example more than 35 %, such as more than 36 %, for example more than 37 %, such as more than 38 %, for example more than 39 %, such as more than 40 %, for example more than 41 %, such as more than 42 %, for example more than 43 %, such as more than 44 %, for example more than 45 %, such as more than 46 %, for example more than 47 %, such as more than 48 %, for example more than 49 %, such as more than 50 %, for example more than 55 %, such as more than 60 %, for example more than 65 %, such as more than 70 %, for example more than 75 %, such as more than 80 %, such as more than 85 %, for example more than 90 %, such as more than 95 %.

The phospholipid source according to the present invention will preferably comprise polyunsaturated fatty acids and monounsaturated fatty acids and optionally also saturated fatty acids. Soy lecithins and □-linolenic acid are particularly preferred. The phospholipid source will preferably comprise at least about 5% phosphatidyl choline,

such as at least 10% phosphatidyl choline. The phospholipid source will more preferably comprise at least about 20% phosphatidyl choline, such as at least about 30% phosphatidyl choline, for example at least about 35% phosphatidyl choline, such as at least about 40% phosphatidyl choline, for example at least about 45% phosphatidyl choline, such as at least about 50% phosphatidyl choline, for example more than about 55% phosphatidyl choline phosphatidyl choline by weight, such as at least 60% phosphatidyl choline, for example at least about 65% phosphatidyl choline, such as at least about 70% phosphatidyl choline, for example at least about 71% phosphatidyl choline, such as at least about 72% phosphatidyl choline, for example at least about 73% phosphatidyl choline, such as at least about 74% phosphatidyl choline, for example more than about 75% phosphatidyl choline, such as at least about 76% phosphatidyl choline, for example at least about 77% phosphatidyl choline, such as at least about 78% phosphatidyl choline, for example at least about 79% phosphatidyl choline, for example more than about 80% phosphatidyl choline, such as at least about 85% phosphatidyl choline, for example at least about 90% phosphatidyl choline, such as at least about 98% phosphatidyl choline, for example 100% phosphatidyl choline by weight.

The phospholipid source will preferably comprise polyunsaturated fatty acids and monounsaturated fatty acids and optionally also saturated fatty acids. The amount of polyunsaturated fatty acids and monounsaturated fatty acids, including the essential fatty acids, may range from 35 to 50, preferably 38 to 44, weight percent of the total amount of the fat source. The essential fatty acids are also called omega-6 and omega-3 fatty acids and include linolic acid and/or linolenic acid (□-linolenic acid). The amount of saturated fatty acids may be from 20 to 30 weight percent, preferably 22 to 26 weight percent, of the total amount of the phospholipid source. In a soy protein containing particle according to the present invention, the phospholipid source usually provides from 5 to 70 percent, preferably 10 to 60 percent, such as from 15 to 50 percent, for example from 20 to 40 percent, such as from 25 to 35 percent of the total energy content of the soy protein containing particle.

The phospholipid source preferably provides at least about 5 percent of the total energy content of the soy protein containing particle, such as at least about 10 percent, for example at least about 15 percent, such as at least about 20 percent, for example at least about 21 percent, such as at least about 22 percent, for example at least about 23 percent, such as at least about 24 percent, for example more than

about 25 percent, such as at least about 26 percent, for example at least about 27 percent, such as at least about 28 percent, for example at least about 29 percent, such as at least about 30 percent, for example more than about 31 percent, such as at least about 32 percent, for example at least about 33 percent, such as at least about 34 percent, for example at least about 35 percent, such as at least about 36 percent, for example at least about 37 percent, such as at least about 38 percent, for example at least about 39 percent, such as at least about 40 percent, for example at least about 45 percent, such as at least about 50 percent, for example at least about 55 percent, such as at least about 60 percent, for example at least about 65 percent of the total energy content of the soy protein containing particle, and preferably less than 70 percent of the total energy content of the soy protein containing particle.

Preferred phospholipid sources are lecithins and even more preferably soy lecithin. Currently preferred lecithin products are manufactured by SKW Nature Products, BioActives, Freising, Germany are marketed under the brand name of Epikuron 100®, Epikuron 130®.

The dietary fibers used in a presently preferred embodiment of the present invention should preferably comprise a mixture of insoluble fibers and water-soluble fibers also referred to as soluble fibers. Soluble fibers have a lowering effect on blood cholesterol levels. Examples of dietary fibers comprising soluble fibers are fibers from apples, bananas, oranges, carrots, oats, and soybeans. The dietary fibers preferably comprise soluble fibers in an amount of about 5 weight percent, such as about 10 weight percent, for example about 15 weight percent, such as about 20 weight percent, for example about 25 weight percent, such as about 30 weight percent, for example about 35 weight percent, such as about 40 weight percent, for example about 45 weight percent, such as about 50 weight percent, for example about 55 weight percent, such as about 60 weight percent, for example about 65 weight percent, such as about 70 weight percent, for example about 75 weight percent, such as about 80 weight percent, for example about 85 weight percent, such as about 90 weight percent, for example about 95 weight percent. The dietary fibers used in the present invention are preferably soybean fibers, more preferably soy cotyledon fibers. Such fibers are derived from dehulled and defatted soybean cotyledon and are comprised of a mixture of soluble and insoluble fibers. Soy cotyledon fibers are distinctly different from soybean fibers derived from soy hulls as well as other fiber sources. Soy cotyledon

fibers are bland tasting, contain no cholesterol, are low in fat and sodium, and they have good water-binding properties and low caloric content.

Soy cotyledon fibers supplied in a fat-modified and low-cholesterol diet are known to further reduce serum cholesterol levels in a subject suffering from mild to severe hypercholesterolemia. The effect is a lowering of the serum levels of total cholesterol including a lowering of the serum levels of LDL-cholesterol. However, HDL-cholesterol and total triglycerides are not significantly affected by soy cotyledon fibers. Soybean fibers, in particular soy cotyledon fibers, are believed to provide a synergistic effect in combination with soy protein and/or with a phytoestrogen compound, such as naturally occurring isoflavones, or to exert a potentiating effect on the soy protein and/or the phytoestrogen compound, said synergistic or potentiating effect being effective in lowering serum levels of lipid and cholesterol in subjects having normal as well as elevated serum levels of total cholesterol and total triglycerides.

Without wishing to be bound by any specific theory it is presently believed that both soluble dietary fibers (working as nutrients) and insoluble dietary fibers (working as bulking agents), in particular from soybean fibers, more particularly soy cotyledon fibers, provide favorable growth conditions for the microflora in the human gut, which makes the microflora more effective in deconjugating isoflavones in the glucoside form to the aglycone form. Isoflavones in the aglycone form are absorbed faster and to a greater extent in the human gut than isoflavones in the glucoside form, and isoflavones in the aglycone form are the biologically more active species in the present context. In view hereof it can be understood that administration of a combination of soy proteins, a high, fixed level of isoflavones and a combination of soluble and insoluble fibers may be effective in providing an increased uptake of isoflavones.

Furthermore, again without wishing to be bound by any specific theory, it is presently believed that both soluble dietary fibers (working as nutrients) and insoluble dietary fibers (working as bulking agents), in particular from soybean fibers, more particularly soy cotyledon fibers, provide favorable growth conditions for the microflora in the human gut, which makes the microflora more effective in converting phosphatidyl serine and phosphatidyl ethanolamine into phosphatidyl choline. This capability to decarboxylate phosphatidyl serine into phosphatidyl ethanolamine by the action of pyridoxal phosphate enzymes and further methylate phosphatidyl ethanolamine into phosphatidyl choline has presently only been proven for bacteria. Phosphatidyl choline

are absorbed faster and to a greater extent in the human gut than phosphatidyl serine and phosphatidyl ethanolamine, and phosphatidyl choline is the biologically more active species in the present context. In view hereof it can be understood that administration of a combination of soy proteins, a phospholipid source having a high fixed level of phosphoglycerides and a combination of soluble and insoluble fibers may be effective in providing increased levels of phosphatidyl choline from a given phospholipid source and hence provide an increased uptake of phosphatidyl choline from a given phospholipid source.

The amount of dietary fibers of the total weight of a soy protein containing particle according to the present invention on a dry basis is preferably more than 2 weight percent, for example at least 4 weight percent, such as at least 6 weight percent, for example at least 7 weight percent, such as at least 8 weight percent, for example at least 9 weight percent, such as at least 10 weight percent, for example at least 11 weight percent, such as at least 12 weight percent, for example at least 13 weight percent, such as at least 14 weight percent, for example at least 15 weight percent, such as at least 16 weight percent, for example at least 17 weight percent, such as at least 18 weight percent, for example at least 19 weight percent, such as at least 20 weight percent, and preferably less than 50 weight percent.

The preferred daily dosage of soybean fibers is from at least 1 g to about 100 g soybean fibers, for example from at least 2 to about 75 g soybean fibers, such as from at least 3 g to about 50 g, for example from at least 4 g to about 40 g, such as from at least 5 to about 30 g, such as from at least 10 g to about 20 g soybean fibers.

Preferred soy cotyledon fiber products manufactured by Protein Technologies International, Inc. are marketed under the brand name of FIBRIM®. Among the various soybean fibers produced under the FIBRIM® brand, FIBRIM® 1020 is particularly preferred because of a particularly pleasant mouth feel and dispersability for dry blended beverage applications. FIBRIM® 2000 is presently preferred for use in ready-made liquids.

Some compositions of isolated soy protein and soy cotyledon fiber are preferred in order to maximize the content of soy protein and isoflavones contained therein namely SUPRO® FXP-HO159, SUPRO® FXP-HO161, FIBRIM® 1450, FIBRIM® 2000 and FIBRIM® 1020 for dry blended beverage applications and SUPRO® FXP-HO159,

SUPRO® FXP-HO161, FIBRIM® 1450, FIBRIM® 2000 and FIBRIM® 1020 for use in ready made liquids.

When a soy protein containing particle according to the present invention is for use in the prevention and/or treatment of type 2 diabetes, the metabolic syndrome and associated cardiovascular diseases, lecithinated fat reduced cacao is particularly preferred. Other preferred carbohydrates for use in a soy protein containing particle according to the present invention for use in the prevention and/or treatment of type 2 diabetes, the metabolic syndrome and associated cardiovascular diseases are polydextrose or saccharose, but these should be limited using other sweeteners like e.g. aspartame.

Vitamins and minerals may optionally be added to a soy protein containing particle according to the present invention in accordance with the limits laid down by health authorities. A soy protein containing particle according to the present invention may comprise all recommended vitamins and minerals. The vitamins will typically include A, B1, B2, B12, folic acid, niacin, panthotenic acid, biotin, C, D, E and K. The minerals will typically include iron, zinc, iodine, copper, manganese, chromium and selenium. Electrolytes, such as sodium, potassium and chlorides, trace elements and other conventional additives may also be added in recommended amounts.

A soy protein containing particle according to the present invention may be used for special dietary use, preferably for lowering serum levels of total cholesterol and/or LDL-cholesterol and/or triglycerides in subjects such as hyperlipidemic patients or normocholesterolemic patients suffering from a cardiovascular disease, and/or for lowering serum levels of glucose and/or insulin and/or total cholesterol and/or LDL-cholesterol and/or triglycerides and/or for increasing glucose tolerance and/or insulin sensitivity and/or for preventing, treating and/or alleviating impaired glucose tolerance and/or insulin secretory failure in diabetic subjects and/or for preventing, treating and/or alleviating an arteriosclerotic condition by reducing the influx of lipoproteins and/or cholesterol and/or triglycerides into the endocelium of the arterial wall of a diabetic subject suffering from a cardiovascular disease. For example, from one to three daily meals of ordinary food can be supplemented or replaced by a soy protein containing particle according to the present invention. Hereby, significant reductions in serum levels of cholesterol and/or LDL-cholesterol and/or triglycerides can be obtained, as well as an improvement of serum HDL/LDL-cholesterol ratio and/or an

increase in serum HDL-cholesterol levels. The soy protein containing particle may provide from about 50 to about 250 kcal per serving.

The soy protein containing particle according to the present invention is effective in lowering levels of cholesterol in normocholesterolemic patients by at least 2%, for example at least 5%, such as at least 8%, for example at least 10%, such as at least 12%, for example at least 14%, such as at least 16%, for example at least 18%, such as at least 20%, for example at least 25%, such as at least 30%. The soy protein containing particle according to the present invention is effective in lowering levels of triglycerides in normocholesterolemic patients by at least 10%, such as at least 12%, for example at least 14%, such as at least 16%, for example at least 18%, such as at least 20%, for example at least 25%, such as at least 30%.

The soy protein containing particle according to the present invention is effective in lowering levels of cholesterol in mildly hypercholesterolemic patients by at least 3%, for example at least 5%, such as at least 8%, for example at least 10%, such as at least 12%, for example at least 15%, such as at least 20%, for example at least 25%, such as at least 30%, for example at least 35%, such as at least 40%, for example at least 45%. The soy protein containing particle according to the present invention is effective in lowering levels of triglycerides in mildly hypercholesterolemic patients by at least 15%, such as at least 20%, for example at least 25%, such as at least 30%, for example at least 35%, such as at least 40%, for example at least 45%.

The soy protein containing particle according to the present invention is effective in lowering levels of cholesterol in severely hypercholesterolemic patients by at least 3%, for example at least 5%, such as at least 8%, for example at least 10%, such as at least 12%, for example at least 15%, such as at least 20%, for example at least 25%, such as at least 30%, for example at least 35%, such as at least 40%, for example at least 45%, such as at least 50%, for example at least 55%, such as at least 60%. The soy protein containing particle according to the present invention is effective in lowering levels of triglycerides in severely hypercholesterolemic patients by at least 20%, for example at least 25%, such as at least 30%, for example at least 35%, such as at least 40%, for example at least 45%, such as at least 50%, for example at least 55%, such as at least 60%.

In another embodiment the present invention provides the use of a soy protein containing particle according to the present invention in the treatment of cardiovascular diseases in the human or animal body in an amount effective in lowering serum levels of total cholesterol and/or LDL-cholesterol and/or triglycerides and/or homocystein and/or increasing the serum HDL/LDL-cholesterol ratio and/or serum HDL-cholesterol levels and/or reducing the influx of cholesterol and/or triglycerides into the arterial wall and/or reducing the amount of oxidized LDL-cholesterol present in the arterial wall and/or preventing, reducing or eliminating fatty streak formation and/or preventing, reducing or eliminating fibrous plaque formation and/or preventing, reducing or eliminating complicated lesion formation and/or reducing or eliminating the risk of a subject contracting angina pectoris and/or reducing or eliminating the risk of a subject contracting a myocardial infarction, and/or alleviating the clinical condition of patients contracting a myocardial infection. The cardiovascular disease is preferably a cardiovascular disease selected from the group comprising hypercholesterolemia, hypertriglyceridemia, other hyperlipidemias, arteriosclerosis, atherosclerosis, arteriolosclerosis, coronary heart disease, angina pectoris, thrombosis, myocardial infarction, and hypertension and more preferred selected from arteriosclerosis and atherosclerosis.

In another embodiment the present invention provides the use of a soy protein containing particle according to the present invention in the treatment of type 2 diabetes and/or the metabolic syndrome in an amount effective in lowering serum levels of total cholesterol and/or LDL-cholesterol and/or triglycerides and/or glucose and/or increasing serum levels of HLDL-cholesterol and/or homocystein and/or reducing the influx of cholesterol and/or triglycerides into the arterial wall and/or reducing the amount of oxidized LDL-cholesterol present in the arterial wall and/or improving glucose tolerance and/or increasing insulin sensitivity and/or alleviating impaired glucose tolerance and/or improving insulin secretion and/or reducing or eliminating fatty streak formation and/or preventing, reducing or eliminating fibrous plaque formation and/or preventing, reducing or eliminating complicated lesion formation and/or preventing, reducing or eliminating the risk of a subject contracting angina pectoris and/or preventing, reducing or eliminating the risk of a subject contracting a myocardial infarction and/or preventing, treating, prophylactically treating, alleviating and/or eliminating hypertension and/or hyperglycemia and/or hyperinsulinemia and/or hypercholesterolemia and/or hypertriglyceridemia and/or arteriosclerosis and/or atherosclerosis and/or arteriolosclerosis in a diabetic subject.

In another embodiment the present invention provides the use of a soy protein containing particle according to the present invention in the treatment of a pulmonary disease in a human or animal body, preferably a disease selected from the group comprising inflammation of the airways, bronchoconstriction, bronchitis, asthma, and small airways diseases, in an amount effective in preventing, treating, prophylactically treating and/or alleviating inflammation of the airways and/or bronchoconstriction and/or bronchitis and/or small airways diseases and/or asthma and/or reducing and/or eliminating mucus hypersecretion and/or dyspnea in a subject suffering from asthma and/or increasing FEV1 of a subject as measured by forced expiratory volume in the first second of expiration.

The present invention also provides a method of preventing, treating, prophylactically treating and/or alleviating by therapy a cardiovascular disease in the human or animal body such as an arteriosclerotic condition of a human or animal body, said method comprising administration of a soy protein containing particle according to the present invention in an amount effective in lowering serum levels of total cholesterol and/or LDL-cholesterol and/or triglycerides and/or homocystein and/or increasing the serum HDL/LDL-cholesterol ratio and/or serum HDL-cholesterol levels and/or reducing the influx of cholesterol and/or triglycerides into the arterial wall and/or reducing the amount of oxidized LDL-cholesterol present in the arterial wall and/or preventing, reducing or eliminating fatty streak formation and/or preventing, reducing or eliminating fibrous plaque formation and/or preventing, reducing or eliminating complicated lesion formation and/or reducing or eliminating the risk of a subject contracting angina pectoris and/or reducing or eliminating the risk of a subject contracting a myocardial infarction, and/or alleviating the clinical condition of patients contracting a myocardial infection. The cardiovascular disease is preferably a cardiovascular disease selected from the group comprising hypercholesterolemia, hypertriglyceridemia, other hyperlipidemias, arteriosclerosis, atherosclerosis, arteriolosclerosis, coronary heart disease, angina pectoris, thrombosis, myocardial infarction, and hypertension and more preferred selected from arteriosclerosis and atherosclerosis.

The present invention also provides a method of preventing and/or treating by therapy type 2 diabetes and/or the metabolic syndrome in a human or animal body, said method comprising administration to said human or animal body of a soy protein containing particle according to the present invention in an amount effective in

lowering serum levels of total cholesterol and/or LDL-cholesterol and/or triglycerides and/or glucose and/or increasing serum levels of HLDL-cholesterol and/or homocystein and/or reducing the influx of cholesterol and/or triglycerides into the arterial wall and/or reducing the amount of oxidized LDL-cholesterol present in the arterial wall and/or improving glucose tolerance and/or increasing insulin sensitivity and/or alleviating impaired glucose tolerance and/or improving insulin secretion and/or reducing or eliminating fatty streak formation and/or preventing, reducing or eliminating fibrous plaque formation and/or preventing, reducing or eliminating complicated lesion formation and/or preventing, reducing or eliminating the risk of a subject contracting angina pectoris and/or preventing, reducing or eliminating the risk of a subject contracting a myocardial infarction and/or preventing, treating, prophylactically treating, alleviating and/or eliminating hypertension and/or hyperglycemia and/or hyperinsulinemia and/or hypercholesterolemia and/or hypertriglyceridemia and/or arteriosclerosis and/or atherosclerosis and/or arteriolosclerosis in a diabetic subject.

The present invention also provides a method of preventing, treating, prophylactically treating and/or alleviating by therapy a pulmonary disease in a human or animal body, preferably a disease selected from the group comprising inflammation of the airways, bronchoconstriction, bronchitis, asthma, and small airways diseases, said method comprising administration to said human or animal body of a soy protein containing particle according to the present invention in an amount effective in preventing, treating, prophylactically treating and/or alleviating inflammation of the airways and/or bronchoconstriction and/or bronchitis and/or asthma and/or small airways diseases and/or reducing and/or eliminating mucus hypersecretion and/or dyspnea in a subject suffering from asthma and/or increasing FEV1 of a subject as measured by forced expiratory volume in the first second of expiration.

The period of treatment is preferably in the range of from 1 to 12 months or more, such as from 2 weeks to 9 months, for example from 3 weeks to 6 months, such as from 4 weeks to 4 months, such as from 6 weeks to 3 months. However, the period of treatment shall not be limited to these periods and may e.g. be longer than 12 months, such as e.g. a lifelong treatment in order to prevent cardiovascular diseases or in order to prevent and/or alleviate type 2 diabetes and/or a cardiovascular disease in connection therewith or in order to prevent pulmonary diseases.

In another embodiment, the present invention relates to the use of a soy protein containing particle according to the present invention as a partial or total diet for an overweight subject, an overweight subject suffering from an arteriosclerotic condition or an overweight subject suffering from a diabetic condition. Obesity is believed to be one of the major causes of diabetes including type 2 diabetes. Overweight subjects, including overweight diabetic subjects, often have increased serum cholesterol levels and increased triglyceride levels and are therefore more likely to develop cardiovascular diseases. However, the present invention is not limited to treating subjects with an increased risk of contracting a cardiovascular disease, i.e. subjects likely to have increased serum levels of cholesterol and/or triglycerides, or to treating obese diabetic subjects with an increased risk of contracting a cardiovascular disease, i.e. obese diabetic subjects likely to have increased serum levels of cholesterol and/or triglycerides. A soy protein containing particle according to the present invention also has substantial serum cholesterol, serum LDL-cholesterol and serum triglyceride lowering effects in subjects having a more normal lipid profile and in diabetic subjects that do not also suffer from overweight. The medical use of a soy protein containing particle to the present invention is not limited to overweight or obese subjects, including diabetic subjects, but may be used for normal weight subjects having increased serum levels of cholesterol and/or LDL-cholesterol and/or triglycerides or for subjects with a cardiovascular condition such as e.g. arteriosclerosis or a related condition who have normal serum levels of cholesterol and/or LDL-cholesterol and/or triglycerides. Such increased serum levels of cholesterol and/or LDL-cholesterol and/or triglycerides may be caused by intake of a diet rich in fats or it may be genetically related.

Example 1

Sponge and dough method for producing US style bread comprising beads

		4 hour		16 hour	
Ingredients	Parts	Sponge	Dough	Sponge	Dough
		wt	wt	wt	wt
Dark Northern Spring Flour	100	1800	1200	1800	1200
Gluten	12.5		375		375
Yeast	4.2	90	36	60	66
Fat	2		60		60
Salt	3.2		96		96
Skim milk powder	3		90		90
Sugar	6		180		180
Fungamyl	80FU		80FU		80FU
Xylanase	0.01		0.3		0.3
Ascorbic acid	0.01		0.3		0.3
Water	110	1200	2070	1200	2070
Sodium stearyl lactylate	0.8		24		24
Abacor beads	60		1800		1800
Results					
Dough			sticky & soft		sticky & soft
Moisture in dough	43.5%				
Oven spring			19		9-11

The sponge of flour, yeast and water is allowed to stand for either 4 or 16 hours. The sponge and water are added to the dry ingredients in the mixer immediately prior to mixing. The beads are used without hydration. The dough is mixed in a CBP unit at 39 kJ/kg over 3 minutes without vacuum and in order to obtain a machineable dough the dough moisture is adjusted to a sudden level. Loaves are baked at 400 g for 21 minutes. The dough is made at 2 moisture levels, the lower level of 43,5% gives good results but the crumb is a little unstable and gives coalescence of cells at the top of the loaves.

Example 2

Sponge and dough method for producing rye bread comprising beads - 1

		4 hour		16 hour	
Ingredients	Parts	Sponge wt	Dough wt	Sponge wt	Dough wt
Flour standard bread flour	70	2100	1200	2100	1200
Rye flour 65% water absorption	30				
Gluten	12.5		375		375
Yeast	3	60	30	30	60
Fat	2		60		60
Salt	3		90		90
Xylanase	0.01		0.3		0.3
Ascorbic acid	0.01	0.06	0.3	0.06	0.3
Water	110	1200	1800	900	2100
Sodium stearyl lactylate	0.8		24		24
Abacor beads	60		1800		1800
Results					
Dough			sticky & soft		sticky
Moisture in dough	44.5%				

The sponge of flour, yeast and water is allowed to stand for either 4 or 16 hours. The beads are used without hydration. The rye bread is mixed in the spiral mixer with 2 minutes at 100 rpm and 12 min. at 200 rpm. Once a water level of 44,5% had been established the dough is moulded as 800g bloomers or baked in rye baskets and baked at 240°C for 30 min. The bread had the characteristic close crumb structure and rye flavour. It is probably denser than a 75/25% wheat/rye mixture and appears more like a 50/50% wheat/rye recipe.

Example 3

Sponge and dough method for producing rye bread comprising beads - 2

	Parts	Sponge	Dough
Ingredients		wt	wt
Dark Northern Spring flour	70	2100	
Rye flour	30		900
Gluten	12.5		375
Yeast	3,0	60	30
Fat	2,0		60
Salt	3,0		90
Xylanase	0.01		0.3
Ascorbic acid	0.003	0.09	
Sodium stearyl lactylate	0.8		24
Abacor beads	42,2		1266
Water	268,6	1262	1304

The sponge of flour, yeast, ascorbic acid and water is allowed to stand for 4 hours at 30°C in a closed bucket. The rye bread is mixed on a 32kg Spiral Mixer for 2 minutes on slow speed and 12 minutes on fast speed. Each piece is scaled by hand to a weight of 930g and moulded into a ball using a conical moulder. The dough pieces are rested for 10 minutes as an intermediate proof. The final mould is done on a Sorensen Moulder with the following dial settings on the CCFRA moulder: rollers 9, width 9,5 and pressure 1,25. After the final moulding the dough pieces are placed in rye baskets dusted with rye flour. The final proof is in a cabinet set at 43°C with 80% R/H and the proving last to touch. After the final proof, the loaves are turned upside down onto baking trays. The dough pieces are then placed on steel trays in a Deck Oven set at 240°C injected with steam for 20 seconds. The baking time is 20 minutes, and after 10 minutes the Damper is pulled whereby the steam is released.

Example 4

Bread wherein the dough is made by use of the spiral mixing method

	Dough			
	1	2	3	4
Ingredients (g)				
Nimrod Flour	1000	1000	1000	1000
Gluten	125	125	250	125
Yeast	42	42	42	42
Salt	31,5	31,5	31,5	31,5
SSL	8	8	8	8
Veron	0,22	0,22	0,22	0,22
Ascorbic Acid	0,1	0,1	0,1	0,1
Beads	480	480	480	670
Water	1039	1039	1030,5	1110
Methods				
State of beads on addition	dispersed in 284g water	dispersed in 284g water	dry	dispersed in 355g water
Point of bead addition (min)	After 4s, 2f	After 2s, 6f	After 4s, 2f	After 4s, 2f
Total Mixing time (min)	4s, 4f	2s, 8f	4s, 4f	4s, 4f
Proof time (min)	44	38	41	45
Results				
Dough score	slightly sticky	sticky	slightly sticky	slightly sticky
Baked height (cm)	13,4	13,5	12,9	12,3
Oven spring (cm)	3,4	3,5	2,9	2,3
Volume (ml)	1529	1675	1486	1354
Specific volume (ml/g)	3,88	4,23	3,67	3,32
Crumb score *	6	7	5	5

s = slow f = fast

*** Mindre end 5 = unacceptable, 6 = has potential, 7, good, 8, very good, 9 = excellent, 10 = perfect**

Veron is blended with flour for 30 minutes before mixing. If the beads are to be pre-hydrated they are dispersed in the specified amount of water for 7 minutes before use. Dry ingredients, except the beads, are placed in the spiral mixer bowl - keeping the salt separate from the yeast. Water is added and mixing commenced. Dry or pre-hydrated beads are added to the mixer at the time specified and mixing resumed. Dough is scored and then scaled at 460g, moulded and left in an intermediate proof cabinet for 10 minutes, before the final moulding. The dough pieces are placed in greased 400g tins and proved to a height of 10cm at the temperature 43°C and 80%

relative humidity and the proofing time is recorded. The bread is baked in a 12 tray reel oven at 244°C for 25 minutes.

Example 5

Bread wherein the dough is made by using CBP mixing

	Dough			
	7	8	9	10
Ingredients (g)				
Nimrod Flour	3000	3000	3000	3000
Gluten	375	375	375	375
Yeast	126	126	126	126
Salt	94,5	94,5	94,5	94,5
SSL	24	24	24	24
Veron	0,66	0,66	0,66	0,66
Ascorbic Acid	0,3	0,3	0,3	0,3
Beads	2010	2010	2010	2010
Water	3330	3430	2975	3330
Methods				
Mixing time (min)	2.12	2.18	2.08	2.12
11watt hours per kilo				
State of beads on addition	dry	dry	dry	dispersed in 1065g water
Point of bead addition	At start of mixing	At start of mixing	At start of mixing	At start of mixing
Proof time (min)	56	50	67	64
Results				
Dough score	slightly sticky	sticky	ok/normal	sticky
Baked height (cm)	12,3	12	11,9	11,3
Oven spring (cm)	2,3	2	1,9	1,3
Volume (ml)	1368	1409	1425	1265
Specific volume (ml/g)	3,33	3,5	3,45	3,12

Veron is blended with the flour for 30 minutes prior to use. If the beads are to be pre-hydrated they are dispersed in the specified amount of water for 7 minutes before use. The water is placed in the Tweedy 35 followed by the dry ingredients, keeping the salt separate from the yeast. Finally, the dry or pre-hydrated beads are added. Mixing is commenced for the time required for 11 watts per kilo to be achieved. Dough is scored and then scaled at 460g, moulded and left in an intermediate proof cabinet for 10 minutes before the final moulding. The dough pieces are placed in greased 400g tins and proved to a height of 10cm at the temperature 43°C and 80% relative humidity. The proof time is recorded. The bread is baked in a 12 tray reel oven at 244°C for 25 minutes.

Example 6

Bread wherein the dough comprising beads and varying ingredients is made by using atmospheric or atmospheric/vacuum mixing in Tweedy 35

	Dark Northern Spring flour							
	Dough							
Ingredients (g)	3/1704	4/1704	5/1704	6/1704	1/1706	2/1706	3/1706	4/1706
Flour	3000	3000	3000	3000	3000	3000	3000	3000
Gluten	375		375		375	180	375	180
Yeast	126	126	126	126	126	126	126	126
Salt	94.5	94.5	94.5	94.5	94.5	94.5	94.5	94.5
SSL	24	24			24	24		
DATA			24	24			24	24
Fat	60	60	60	60	60	60	60	60
Xylanase	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Fungal Amylase	5.1	5.1	5.1	5.1	5.1	5,1	5,1	5,1
Ascorbic Acid	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Beads	1800	1800	1800	1800	1800	1800	1800	1800
Water	3281	2718	3281	2718	3281	2988	3281	2988
Methods								
Mixing	A	A	A	A	A/V	A/V	A/V	A/V
Proof time (min)	48	55	52	70	55	50	53	48
Results								
Dough score	soft & sticky	sticky	soft & sticky	sticky	soft	soft	soft	soft
Baked height (cm)	13,0	10,0	12,4	9,4	13,3	11,6	12,4	11,1
Oven spring (cm)	3,0	0,0	2,4	0,0	3,3	1,6	2,4	1,1
Volume (ml)	1462	1080	1369	1031	1538	1342	1430	1216
Specific volume (ml/g)	3,60	2,60	3,37	2,49	3,8	3,25	3,48	2,93

5 A atmospheric mixing A/V Atmospheric/Vacuum mixing

	Strong Bread Making flour					
	Dough					
Ingredients	7/1704	8/1704	9/1704	10/1704	5/1706	7/1706
Flour	3000	3000	3000	3000	3000	3000
Gluten	375		375		375	375
Yeast	126	126	126	126	126	126
Salt	94.5	94.5	94.5	94.5	94.5	94.5
SSL	24	24			24	
DATA			24	24		24
Fat	60	60	60	60	60	60
Xylanase	0.3	0.3	0.3	0.3	0.3	0.3
Fungal Amylase	5.04	5.04	5.04	5.04	5.04	5,04
Ascorbic Acid	0.3	0.3	0.3	0.3	0.3	0.3
Beads	1800	1800	1800	1800	1800	1800
Water	3310	2747	3310	2747	3310	3310
Methods						
Mixing	A	A	A	A	A/V	A/V
Proof time (min)	50	75	56	75	48	51
Results						
Dough score	soft & sticky	soft & sticky	soft & sticky	soft & sticky	soft	soft
Baked height (cm)	12,3	8,6	12,0	9,0	12,1	11,7
Oven spring (cm)	2,3	0,0	2,0	0,0	2,1	1,7
Volume (ml)	1337	933	1314	906	1329	1313
Specific volume (ml/g)	3,27	2,26	3,24	2,18	3,23	3,24

A atmospheric mixing A/V Atmospheric/Vacuum mixing

	Nimrod flour						
	Dough						
	11/1704	12/1704	13/1704	14/1704	9/1706	10/1706	11/1706
Ingredients (g)							
Flour	3000	3000	3000	3000	3000	3000	3000
Gluten	375		375		375	180	375
Yeast	126	126	126	126	126	126	126
Salt	94.5	94.5	94.5	94.5	94.5	94.5	94.5
SSL	24	24			24	24	
DATA			24	24			24
Fat	60	60	60	60	60	60	60
Xylanase	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Fungal Amylase	4,9	4,9	4,9	4,9	4,9	4.9	4.9
Ascorbic Acid	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Beads	1800	1800	1800	1800	1800	1800	1800
Water	3287	2724	3287	2724	3287	2994	3287
Methods							
Mixing	A	A	A	A	A/V	A/V	A/V
Proof time (min)	53	75	50	69	47	55	49
Results							
Dough score	soft & sticky	soft & sticky	soft & sticky	soft & sticky	soft & sticky	soft & sticky	soft & sticky
Baked height (cm)	12,1	8,6	11,6	8,5	12,1	10,8	11,7
Oven spring (cm)	2,1	0,0	1,6	0,0	2,1	0,8	1,7
Volume (ml)	1353	937	1230	870	1349	1200	1314
Specific volume (ml/g)	3,29	2,24	2,96	2,09	3,24	2,88	3,18

A atmospheric mixing A/V Atmospheric/Vacuum mixing

Veron is blended with flour for 30 minutes prior to use. The water is placed in the Tweedy 35 followed by the dry ingredients, keeping the salt separate from the yeast and finally the beads are added. When using Atmospheric mixing in Tweedy 35 the mixing is commenced for the time required for 11 watt hours per kilo to be achieved. When using Atmospheric/Vaccum mixing in Tweedy 35 a 15" vacuum is pulled at 48watt hours. Dough is scored and then scaled at 460g, moulded and left in an

intermediate proof cabinet for 10 minutes, before the final moulding. The dough pieces are placed in greased 400g tins and proved to a height of 10cm at the temperature 43°C and 80% relative humidity. The proof time is recorded. The bread is baked in a 12 tray reel oven at 244°C for 20 minutes.

Bread made without gluten gives a very poor volume. Bread made using gluten gives a better volume when SSL is used as opposed to DATA. Dark Northern Spring Flour (DNS) produces bread with a better volume than Strong Bread Making Flour, which gave a better volume than Nimrod Flour. The bread giving the best volume, texture and taste comprises DNS flour and 375g gluten and is mixed by pulling a 15" vacuum at 48watt hours and baking for 20 minutes at 244°C. The bread exhibits a darker than normal crust.

Example 7, Abacor Beads

The product contains the following raw materials per 100 kg:

Abacor powder blend:	75 kg
Wheat starch:	21 kg
Maltodextrine (DE 15):	4 kg
Total:	100 kg

The raw materials are blended in a suitable mixer for example a horizontal double-ribbon blender or a vertical screw mixer. A tumbler should preferably not be used

The mixing procedure is performed as follows:

Weigh out the amounts of the raw materials as described above.

Add the raw materials in 2-3 layers and start with adding the Abacor powder

blend to the bottom of the mixer.

Mix for 15 to 20 minutes depending of the type of blender used.

Comments:

The humidity in the production rooms should be maintained within 40-55% RH during the production. All ingredients are fed into the mixture through a combination of magnetic strips and 16-30 mesh screen.

The extrusion takes place in a twin screw mixer, for example the types from:

APV/UK - sizes:	50, 65 and 90 millimetre barrel diameter
Clextral/France – sizes:	same barrel sizes
Buhlan/Switzerland – sizes:	Biex 50, 65 and 90

The 50 size is a pilot or small production size, while the other two are more normal production sizes.

Screw configurations and main production parameters:

Screw elements:

Elements	Alternative 1	Alternative 2
Feed screw	16 D	16 D
Paddles	6*60 forward	6*60 forward
Feed screw	2 D	2 D
Paddles	6*60 reverse	6*60 reverse
Single lead	0.5 D	0.5 D
Paddles	4*60 reverse	6*30 reverse
Single lead	0.5 D	0.5 D
Paddles	6*30 reverse	4* 60 reverse
Feed screw	1 D	1 D

Scale up variables:

Variable	Pilot scale	Production
Barrel diameter, mm	50	90
Screw elements	6*30 reverse	6*30 reverse
Die hole area, sq. mm	12 (4*2 mm)	100 (34*2 mm)
Screw speed, rpm	260	240
Moisture, %	30	31
Barrel temperature °C	115	100
Feed rate, kg/hr	50	500

After drying:

The beads must be dried after the extrusion process to get the final water content of approx. 4 % on the beads.

The best suitable type of drier for these beads is a fluid bed drier, preferably a continuous fluid bed with a heating and a consecutive cooling section.

It is of vital importance not to loose active ingredient that the conditions are as gentle and efficient as possible. This means a shortest possible heat exposure to the beads as possible (short heating process followed by a shortest possible cooling period).

The preferred conditions are:

Air temperature:	150-160 °C
Layer thickness cm:	preferably not thicker than 10-15
Residence time in heating zone:	30 - 40 seconds

Immediate cooling in the cooling section:

Air temperature:	preferably approx. 10 °C
Residence time:	30 seconds

In-process control:

All production parameters are controlled regularly throughout the production. All essential parameters are registered by time intervals and follow the production batches.

Beads control:

Samples are taken by certain intervals, for ex. every hour an controlled for water content, colour, flavour/odour and bulk density.

QC are responsible for these controls and for the approval and release.

Packaging:

The beads are filled in suitable bulk packaging units and can be shipped after release from QC.

Example 8

Product Description: Abacor Beads are a crunchy source of the Abacor blend ideal for nutritional bars and cereals based on soy components.

The product contains: Isolated soy protein, soy fiber, soy phospholipids, wheat starch, maltodextrine.

Nutrition: All raw materials are based on high quality raw materials. The soy raw materials contain soy protein with a P.D.C.A.A.S (Protein Digestibility Corrected Amino Acid Score) equal to 1.0, the highest possible score. It is equivalent in protein quality to milk and egg protein. The soy fiber contains a high quality of Cotyledon fiber and is free of oligo saccharides. The phospholipids have a phosphatidylcholin content of min. 20-25%. The other ingredients are chosen from pure raw materials of high and defined quality. All components are IP qualities.

Chemical analysis and requirements:

Moisture:	4 %
Soy protein:	50 %
(N x 6.25, as is)	
Total protein:	less than 55 %
Fat:	less than 7 %
Fibers:	11 %
Bead size:	maximum 4 mm

Microbiological requirements:

Standard Plate Count:	maximum 5000/g
Salmonella (by test):	negative/1 g
Coliforms	maximum 10/g
E.Coli (by test).	Negative/25 g
Yeast-Mold:	maximum 100/g

Nutritional values:

g/100 g after drying to 4% water:

Total protein	51.2 g
Soy protein	50.9 g
Carbohydrates	24.1 g
Fat	6.2 g
Saturated fat	1.0 g
Monounsaturated fat	1.6 g
Polyunsaturated fat	2.2 g
Dietary fiber	9.9 g
Water	4.0 g
Energy	361 kcal / 1509 kJ

Minerals:

Sodium	0.9 g
Potassium	0.3 g

	Calcium	0.2 g
	Copper	0.8 mg
	Iron	10.2 mg
	Phosphorus	0.6 g
	Zinc	2.5 mg
Vitamins:		
	Riboflavin (B2)	0.1 mg
	Biotin	0.02 mg
	Niacin	0.2 mg
	Panthothenic acid	0.1 mg
	Folacin	0.1 mg

Example 9 - Pilot scale preparation of new ISP's

Processing Conditions

The process and process conditions of this example were based on Procedure 3 from EXAMPLE 3. One important difference was that no second extraction at pH 5.4 was carried out. The preparation of the ISP was carried out in a number of batches which were combined to give the products as the Final Mix (FM).

Procedure

Table 1: Separation Scheme for Isolate

Step	Action	Fractions	Time (min)
1	Soy flour (40 kg) was dispersed in water (300l) at 20 to 21°C in Tank 1 with a portion of anti-foam FDP (75 ml).		~ 10
2	The mixture was adjusted to pH 8.0 with 2 M KOH (~3.6 l)		~ 5.0
3	Extraction with continuous stirring (30 min.) was followed by holding without stirring (30 min.)		60
4	The slurry was centrifuge to remove solids with feed rate of 726 l/h and a pressure of 4.25 kg/cm^2 into Tank 2. The partially cleared slurry was re-centrifuged and returned to Tank1. The fibre-rich solids collected by the centrifuge were discarded.	Fibre + high Mwt. proteins	~ 90
5	Small ice pieces (48kg) were added to bring temperature ~ 7.0° C		~ 5.0
6	The pH of the solution was reduced to 5.4 with 5.5 M HCl (~1.7 l)		~ 5.0
7	Precipitation was allowed to occur without stirring		90
8	Isolate was separated by centrifuging at 726 l/h and a pressure of 4.25 kg/cm^2 from Tank1 to Tank 2 and then back to Tank 1. The precipitate recovered from	ISP, fraction 1	~ 90

	the centrifuge. Antifoam FDP (75 ml) was added during the separation.		
9	Small ice pieces (12 kg) were added to the solution to bring temperature ~ 10° C		~ 3.0
10	The pH was reduced to 3.5 with 5.5 M HCl (approximately 3.7l)		~ 5.0
11	Precipitation was allowed to occur without stirring		60
12	The isolate was separated by centrifugation at a feed a rate of 726 l/h and a pressure of 4.25 kg/cm^2 in a single pass from Tank 1 to Tank 2. The insoluble isolate was collected and the liquor of solubles discarded.	ISP, fraction 2	~ 40
13	Both isolates were combined in a 25l-vessel and mixed with a Silverson. Samples were collected for microbiology, protein and moisture.		~ 10
14	The pH was raised to between 6.0 to 6.5 with a concentrated solution of KOH (415g in approx. 500 ml water).		~ 10
15	Portions (6.0 kg) of the slurry were deposited in freezing trays (1000mm x 495mm) lined with plastic sheets and frozen at -21°C in walk-in freezer.		~ 60

RESULTS

The results from the analysis if the FM for moisture, fibre, ash, and protein content.

Table 2. Analysis of freeze-dried isolate

	Moisture (%)	Fibre	Fibre dry basis	Ash	Ash (dry basis)	Protein (as is)	Protein (dry basis)	Fibre Ash+Prot
Final mix FM	**5.3**	**4.30**	**4.5**	**6.64**	**7.0**	**77.0**	**81.3**	**92.8**

Physical analysis of free-dried isolate

Differential thermal analysis

Table 3: DSC data for flour, isolate and some commercial isolates

	Weight used in DSC pan (mg)	Enthalpy Peak 1 (J/g dry protein)	Enthalpy Peak 2 (J/g dry protein)
Commerciall soy flour	46.3	1.48	5.64
Soya isolate final mix	32.5	1.10	5.41
A - FXP H0161	52.8	0	0
D - XT 10	34.6	0	0

The two graphs for soy flour and soy isolate FM are plotted on the same graph (Figure 1) with the same scale for the peaks. The difference in baseline due to sample mass has been reduced by shifting the flour graph downwards by 7.0 units.

As shown in the graphs depicted in Figure 2: two commercial available qualities of ISP from Du Pont Protein Technologies, the curves are without peaks, indicating that there is not any un-denatured globular protein structure left in the products.

The PAGE data showed strong bands for the 7 and 11 S proteins that were more pronounced than for the flour, supporting the DSC finding.

Table 4: Values of the peak areas shown in graph of densitometry in the soy flour and the FM Isolate at equivalent protein levels for loading the PAGE.

Mol. weight in Da	79.5	71.7	64.6	43.1	29.3	14	9.6
Protein type	7S	7S	7S	7S	11S	11S	PEPTIDES
Soya flour OD value	49	81	125	118	160	176	23
Isolate FM OD value	50	105	135	180	210	210	20

OD is the optical density reading of the scanning device used to "read" the gels.

Solubility of isolated precipitated at 5.4 and 3.5

Table 5: Results of analysis of commercial isolates for %protein solubility

Samples		Total protein, %	Soluble protein, %		% soluble
A	FX H0 161	84.5	46.5		55
B	Supro 760	84.5	23		27.2
C	661	87.5	19		21.7
D	XT10	82	34		41.5
E	FX H0 159	77.5	40		51.6
F	219	83	43.5		52.4
G	219D	82.56	44		53.3
H	LH (Bunge)	85	35.5		41.8
I	NB (Bunge)	86.5	24		27.8
J	Profam 940 (ADM)	84	28		33.3
K	Fibrim 1020	8.5	3		35.3
L	Supro ST	79	16		20.3
M	Supro 770LN	84.5	25		29.6
N	Supro XT34	80	22		27.5
Isolates from Example 9 batches 18/20		**82.1** **80.1**	**78.8** **77.7**		**96.0** **97.1**

The solubility of the isolates prepared according to this example were approximately 96-97% after freeze-drying showing no denaturation had occurred

Isoflavon analysis

Table 6: Selected values for comparison on total isoflavon level

Identification	Genistein	Daidzein	Glycitein	Total as Aglycon mcg/g	Total as Glycoside mg/g
Commercial soy flour used for preparing ISP	770	654	13	1437	2.44
ISP	667	641	94	1402	2,38

From the above data it is clear that the process according to the present invention allows for the preparation of soy protein products retaining almost all the isoflavones present in the starting material. This is in line with the undenatured state of the soy protein as the isoflavones are associated with the interior of the proteins and would thus remain associated with the proteins when the globular structure is intact.

PAGE densitograms:

The isolate was run at 3 concentrations of material added to the gel. In general terms the O.D. values are linear from 0.01 to 0.8 and it is unwise to use higher values. The most diluted sample gave the best separation of the peaks and the densitogram from this was consequently used for further analysis. This was for the isolate obtained by mixing 0.025ml of the extract with 0.375ml of Laemmli buffer.

The same was true for the densitograms for the soy flour. The lowest concentration of material added to the gel gave a better separation.

Table 7: 7 and 11S protein content in Flour and ISP

Product	7S	11S	Other, soy proteins
Flour, %	28	29	43
ISP, %	34	39	27

Table 8: Composition of the basic components in 7S and 11S of the ISP

	7 S			11S	
Components	α'	α	β	A	B
Amounts % of total prot.	9	12	13	19	20

The amounts of 7 and 11S proteins are considerably increased in concentration during the processing. This is because the highest molecular weight proteins, the 15 S fraction will be separated out together with the insoluble fibres and much of the 2S fraction is more water-soluble and will be a part of the water solution and removed.

The SDS-PAGE data indicated that the second washing and precipitation of ISP at pH 5.4 would have contributed to higher yield of ISP, but also to an increased amount of 7S as this ISP fraction showed a different relation between 7 and 11S than from the first precipitation. The result would most probably have been a result of more equal quantities of 7 and 11S than shown in the Table 7 above.

Material and Equipment.

1. Two deliveries (1000 kg) of soy flour were purchased from Cargill as lots 1 and 2. Lot 1 was processed as batches Nos.14 to 31 and lot 2 as batches Nos.32 to 40.
2. Reagent grade Hydrochloric acid (specific gravity 1.18) and
3. Potassium hydroxide (56.1g/mol.) was purchased from BDH and tap water was used to make the slurry.

4. A foam-depressing reagent, antifoam FDP, was obtained from Basildon Chemical Company Ltd., Kimber Road Abingdon Oxon., OX14 1RZ.

The table below shows the main data for the two batches of Soy Flour used as raw material for the process and the pilot scale production:

Table 9. Soy flour -starting material

Detail		
Name	De-fatted soy Provabis 200/80	De-fatted soy Provabis 200/80
Batch number	820423	8198859
Production	18/04/02	18/04/02
Protein, %	> 52	> 52
Fibre, %	3.0-3.5	3.0-3.5
Oil, %	0.7-1.2	0.7-1.2
Moisture, %	< 10	< 10
Total plate count, ln	max. 5.2	max. 5.2
Enterobacteriacae, ln	max. 4.0	max. 4.0
Salmonella	nil	nil
Granulation %	< 6	< 6
Used in batches	1-13	14-40

Equipment

1. Centrifugal separators from Westphalia Separators, Model SA 7-06-476 with self-cleaning bowl and a set of 69 separating cones, and
2. A paddle mixer was used to make the flour/water slurry and for mixing during pH adjustment.
3. A Silverson mixer (without shearing element) model D, Silverson Machine Ltd, Waterside, Chesham, Bucks, HP5 1PQ was used to mix the isolates during pH adjustment.
4. APV 454 litres capacity steam jacketed kettles were used as holding tanks.
5. A NORD, model SK 20R150U90L/433, CIP lobe pump was used to feed slurry to the separator.

6. An Edwards freeze Dryer Modulyo was used for small-scale drying of isolates.
7. Commercial Freeze Drying was performed with N° Three and N° Seven freeze dryers.

Freeze-Drying

Comment:

Freeze-drying was chosen as a suitable method in this case. To avoid microbiological growth in all produced ISP in the established pilot process was frozen on trays immediately after production. Instead of having to defrost all material again with increased microbiological risk, we decided to use freeze drying in this particular case. Freeze-drying is also a rather gentle drying method.

Generally all kind of drying methods can be used, but the drying conditions must in all cases be chosen carefully to avoid further denaturation. The standard spray drying method is preferred for full production scale operations. But in such cases it is an advantage not to dry to low water level as this might influence the dispersion and flavour properties of the final product.

Laboratory scale to obtain analytical values

Samples were frozen at -21°C. Edwards freeze Dryer Modulyo was used for drying the isolate at lab scale. Samples were kept at -55°C and a vacuum pressure of 10^{-1} mbar (0.1mm Hg) was used. It took 4 to 5 days to dry even very small samples.

Commercial Freeze Drying:

The process was undertaken in two dryers, N° Three and N° Seven designed and built by Commercial Freeze Drying Ltd. Both dryers were CFD. N° Three has 28 trays of approximately 1000mm x 495mm and N° Seven holds 102 trays of the same size.

The frozen product was received by Commercial Freeze Dry Ltd. was held in cold storage at -20°C. Clean trays were then lined and the product weighed onto them at 5 kg/tray. The trayed product was then held overnight at -20°C to stabilise and the freeze dryer was cleaned with Commercial Freeze Dry Ltd. normal cleaning procedures and cooled to -20°C ready for loading. After loading a vacuum was created in the freeze dryer and it was run at a vacuum pressure < 2 mbar. Since the product

was heat sensitive, a heat profile was run which prevented the product from reaching a temperature of greater than +30°C. This considerably extended the drying time.
First batch of 140 kg of wet product was dried In N° Three dryer on 5th September through 7th September. Dried product was then ground with an Apex comminuting mill model 114 type S2 at a fast hammer rotation speed and a screen aperture of 0.125".

After examination of the powder sample, it was too coarse and to reduce the particle size further, the finished product screen aperture was reduced to 0.107"for subsequent milling of the product. The product was then dispatched to CCFRA.

The remaining wet product was dried in five lots of 140 kg each in N° Three dryer and two lots of 510 kg each in N°Seven dryer. The dried product was then ground using 0.107" screen and dispatched to CCFRA in sealed in plastic sacks for further processing. Grinding screens were restricted by concerns for the temperature sensitivity of the product. A fine screen necessary to obtain particles < 150 um caused a build up of heat in the product, so a larger screen was used.

EXAMPLE 10

Comparison of the clinical effect of ingesting undenatured soy protein according to the present invention or a commercial ISP with a high isoflavone content.

Two Isolated soy protein products A (SuproSoy) and B (Undenatured ISP) were studied with a placebo C (casein) in a randomized placebo-controlled trial according to GCP with respect to their lipid lowering effects.

Study details: The patients took for 8 weeks daily 25g of the 3 products in 2 dosages in the morning and in the evening. The products were dissolved in water. Intermediate visits occurred after 2 and 4 weeks.

Patients: 120 patients of both sexes (73 women and 47 men in the age of 32 to 70) were included if they fulfilled the inclusion criteria of 200-300mg/dl or 5.2-7.8 mmol/l total cholesterol.

Statistics: For the primary (total cholesterol) and secondary parameters (LDL- and HDLcholesterol) the mean differences between the first and fourth visit were tested using the group comparison analysis of variance.

Dropouts: During the study the following dropouts occurred: Group A: 8 cases, group B: 10 cases, and group C: 11 cases; from those only partial results are available. Therefore the analysis was done for the per protocol group; in addition a intention-to-treat analysis was performed.

Side effects: No severe side effects occurred.

Description of patients: 120 patients included; 91 finished per protocol.

Results: Of the protocol analysis:
The mean age was 55.1 years
Weight: the weight increase during the study was 0.2-0.6 kg

1) total cholesterol:

Difference visit 4 vs visit 1:

A: - 12.8 mg/dl -5.0%
B: - 24.3 mg/dl -9.4%
C: + 1.1 mg/dl +0.4%

Percentage changes Active vs Placebo:

A-C: -5.4%
B-C: -9.8%

Significances:

A:B O.017
A:C 0.013
B:C 0.001

2) LDL cholesterol

Difference visit 4 vs visit 1:

A: -12.3 mg/dl - 7.5%
B: -19.4 mg/dl -11.8%
C: - 5.8 mg/dl - 3.6%

Percentages changes Active vs Placebo:

A-C: 3.9 %
B-C: 8.2 %

Significances:

A:B 0.081
A:C 0.159
B:C 0.006

3) HDL cholesterol

No significant changes occurred

Summary:

The new undenaturated ISP formulation has proven to be significantly more effective to reduce total cholesterol than SuproSoy ISP. LDL cholesterol was significantly lowered with the new undenaturated ISP, but not for SuproSoy, in 91 patients with hypercholesterolemia in 8 weeks in a randomized placebo-controlled trial.

The percentage improvement of total cholesterol of the new undenaturated ISP was 9.8% compared to SuproSoy ISP with 5.4%; an improvement of over 80%. The improvement of LDL cholesterol was 8.2% for the new undenaturated ISP compared to 3.9% for SuproSoy, an improvement of over 100%.

CLAIMS

1. Bread comprising soy protein in an amount of at least 8% by weight of the bread.

2. Bread according to claim 1 comprising phytoestrogens in an amount of at least about 0,10% by weight of the soy protein source.

3. Bread according to claim 2 wherein at least one of the phytoestrogen compounds is selected among isoflavones.

4. Bread comprising:
   a) Soy protein in an amount of at least 4% by weight of the bread.
   b) Soy dietary fibre in an amount of at least 0,9% by weight of the bread.
   c) Soy phospholipids in the amount of at least 0,07% by weight of the bread.

5. Bread according to claim 4 comprising phytoestrogens in an amount of at least about 0,10% by weight of the soy protein source.

6. Bread according to claim 5 wherein at least one of the phytoestrogen compounds is selected among isoflavones.

7. Bread according to any of claims 4 to 6 comprising a phosphatidyl choline compound in an amount of at least 10% by weight of the soy phospholipid source of the bread.

8. Bread according to any of claims 4 to 7 wherein the soy phospholipid is lecithin.

9. Bread according to any of claims 4 to 7 wherein the soy dietary fibre is cotyledon.

10. Bread according to any of claims 1 to 9 comprising an emulsifier such as Sodium Stearoyl Lactylate (SSL) in an amount of at least 9% by weight of the soy fibre content of the bread.

11. Bread according to any of claims 1 to 10 comprising exogenous added gluten in an amount of more than 101% by weight of the soy fibre content of the bread.

12. Bread according to any of claims 1 to 11 comprising an amylolytic enzyme preparation in an amount of at least 0,1% by weight of the soy fibre content of the bread.

13. Bread according to claim 12 wherein the amylolytic enzyme preparation has additional transglutaminase and hemicellulase activity.

14. Bread according to any of claims 4 to 13 wherein the soy protein, soy dietary fibre and soy phospholipids are incorporated as a blend.

15. Bread according to claim 14 wherein the blend is pre-hydrated with at least 7g liquid per gram of soy fibre in the bread.

16. Bread according to claim 14 wherein the blend is dispersed in liquid before being incorporated to the dough.

17. Bread according to claim 16 wherein the liquid is selected from the group consisting of water, milk and juice.

18. Bread according to claim 17 wherein the liquid is water.

19. Bread according to any of claims 1 to 3 wherein the soy protein is incorporated as soy protein containing particles or beads.

20. Bread according to any of claims 4 to 18 wherein the soy protein, soy dietary fibre and soy phospholipids are incorporated as soy protein containing particles or beads.

21. Bread according to any of claims 19 and 20 wherein the beads further comprise starch such as wheat starch, rice starch, potato starch and maize starch.

22. Bread according to claim 21 wherein the starch is wheat starch.

23. Bread according to any of claims 19-22 wherein the beads further comprise a sugar compound such as maltodextrine.

24. Bread according to claim 23 wherein the sugar is maltodextrine.

25. Bread according to any of claims 19-24 wherein the dough moisture is adjusted to at least 43%.

26. A method for manufacturing bread comprising soy protein in an amount appropriate to achieve a content of at least 8,4% by weight of the bread wherein said method comprises a step of pre-hydrating the soy protein prior to incorporating it to the dough.

27. A method according to claim 26 wherein said soy protein is pre-hydrated by mixing with liquid.

28. A method according to claim 27 wherein said soy protein is pre-hydrated by mixing with liquid without soaking.

29. A method according to claim 26 wherein said soy protein is pre-hydrated by dispersing it in liquid for about 30 seconds.

30. A method according to any of claims 26 to 29 wherein the liquid is selected from the group consisting of water, milk and juice.

31. A method according to claim 30 wherein the liquid is water.

32. A method for manufacturing bread using a blend comprising

- soy protein in an amount appropriate to achieve a content of at least 4,9% by weight of the bread
- soy dietary fibre in an amount appropriate to achieve a content of at least 0,9% by weight of the bread
- soy phospholipids in an amount appropriate to achieve a content of at least 0,07% by weight of the bread

wherein said method comprises the step of pre-hydrating the blend prior to incorporating it to the dough.

33. A method according to claim 32 wherein said blend of soy protein, soy dietary fibre and soy phospholipids is pre-hydrated by mixing with liquid.

34. A method according to claim 33 wherein said blend of soy protein, soy dietary fibre and soy phospholipids is pre-hydrated by mixing with liquid without soaking.

35. A method according to claim 32 wherein said blend of soy protein, soy dietary fibre and soy phospholipids is pre-hydrated by dispersing it in liquid for about 30 seconds.

36. A method according to any of claims 32 to 35 wherein the liquid is selected from the group consisting of water, milk and juice.

37. A method according to claim 36 wherein the liquid is water.

38. A method for manufacturing bread comprising soy protein wherein said method comprises the steps of incorporating the soy protein into soy protein containing particles or beads and incorporating the soy protein particles or beads into the dough.

39. A method for manufacturing bread comprising soy protein, soy dietary fibre and soy phospholipid wherein said method comprises the steps of incorporating the soy protein, soy dietary fibre and soy phospholipid into soy protein containing particles or beads and incorporating the beads into the dough.

40. A method according to any of claims 38 and 39 wherein the soy containing particles or beads are produced by extrusion.

41. A method according to claim 40 wherein the soy protein containing particles or beads are produced by extrusion cooking with starch.

42. A method according to claim 40 wherein the soy protein containing particles or beads are produced by extrusion with pregelatinised starch and drying

43. A method according to any of claims 41 and 42 wherein the starch is chosen from a vegetable source such as wheat, rice, potato and maize.

44. A method according to claim 43 wherein the starch is wheat starch.

45. A method according to claim 40 wherein the soy protein containing particles or beads are produced by extrusion with thermo-labile gelling agents and further thermal treatment with microwaves.

46. A method according to claim 40 wherein the soy protein containing particles or beads are produced by extrusion with thermo-labile gelling agents and further thermal treatment with hot air.

47. A method according to claim 40 wherein the soy protein containing particles or beads are produced by use of a cold chemical gelling agent.

48. A method according to any of claims 38 to 47 wherein said soy protein containing particles or beads are pre-hydrated before being incorporated into the dough.

49. A method according to claim 48 wherein said soy protein containing particles or beads are pre-hydrated for 7 minutes in liquid before being incorporated into the dough.

50. A method according to any of claims 48 and 49 wherein the liquid is selected from the group consisting of water, milk and juice.

51. A method according to claim 50 wherein the liquid is water.

52. A method according to any of claims 38 to 47 wherein the soy protein containing particles or beads are dry when being incorporated into the dough.

53. A method according to any of claims 26-52 wherein said blend, soy protein containing particles or beads are added to the mixer immediately prior to the mixing procedure.

54. A method according to any of claims 26-52 wherein said soy blend, soy protein containing particles or beads are added to the mixer during the mixing procedure.

55. A method according to any of claims 53 and 54 wherein the moisture level of the dough is adjusted in order to make the dough machineable.

56. A method according to claim 55 wherein the moisture level of the dough is adjusted to at least 43%.

57. A method according to any of claims 55 and 56 wherein the bread is manufactured by the sponge and dough method.

58. A method according to claim 57 wherein the sponge comprises wheat flour, yeast and water.

59. A method according to claim 58 wherein the sponge is allowed to stand before the dough is mixed.

60. A method according to claim 59 wherein the sponge is allowed to stand for at least 4 hours before the dough is mixed.

61. A method according to any of claims 55 and 56 wherein the dough is made by use of spiral mixing.

62. A method according to claim 61 wherein the mixing procedure comprises mixing at various velocities.

63. A method according to claim 62 wherein the mixing velocities are chosen from a group comprising slow mixing at 100 rpm. and fast mixing at 200 rpm.

64. A method according to any of claims 55 and 56 wherein the dough is made by use of CBP mixing.

65. A method according to claim 64 wherein the mixing is commenced for the time required for 11 watts per kilo to be achieved.

66. A method according to any of claims 55 and 56 wherein the dough is made by use of atsmospheric or atmospheric/vacuum mixing.

67. A method according to claim 66 wherein the mixing is commenced for 2-3 minutes till approx. 10,8-11 watt hours per kilo is achieved. When using atmospheric/vaccum mixing a 15" vaccum is pulled at 48 watt hours.

68. A method according to any of claims 55 and 56 wherein an amymolytic enzyme preparation is added together with the remainder dry ingredients when mixing the dough.

69. A method according to any of claims 55 and 56 wherein an amymolytic enzyme preparation is blended with the flour prior to mixing the dough.

70. A method according to claim 69 wherein the amymolytic enzyme preparation is blended with the flour for 30 minutes before mixing the dough.

71. Method for the manufacture of soy protein containing particles characterised by: a) using native soy protein in the form of an ISP or a soy flour, flakes or similar and mixing of this with soy fiber, soy lecithin and 10 to 25 % wheat starch, salt and maximum 4 % of maltodextrine, b) producing the particles as extruded particles in a traditional extruder using water during the process in a total of 20-35 % in total and temperatures on the barrel of a maximum 90 °C and a temperature of the die of a maximum 105 °C, and c) drying the particles in a fluid bed drier, on a belt dryer or in a trey dryer at an air temperature of maximum 60 °C or in vacuum.

72. Method for the manufacture of soy protein containing particles characterised by: a) using native soy protein in the form of or a soy flour, flakes or similarand mixing of

this with soy fiber, soy iecithin and 4-8 % maltodextrine and salt, b) mixing the mixture of a)thoroughly by adding a water solution with pregelled starch, guar gum and SSL (maximum 15 % solution) in a closed twin screw mixer and optionally adding an agglomeration additive to the powder mixture and then only adding water during the agglomeration, c)pressing the wet material through a plate with suitable holes to fit the wanted size on the beads with a temperature on the material at the outlet end of maximum 55 °C, and d) drying the particles are in a fluid bed drier, on a belt dryer or in a trey dryer at an air temperature of maximum 60 °C or in vaccum.

73. Method for the manufacture of soy protein containing particles according to any of claims 71-72, further characterised by making use of a controlled Maillard reaction during processing.

74. Soy protein containing particles obtainable by a method accoridng to any of claims 71-73.

75. Soy protein containing particles characterized by having a particle size of 300 micron.

76. Soy protein containing particles characterized by having a particle size of 800 microns.

77. soy protein containing particles according to any of claims 74-76 further characterised by having a bulk density of 50 to 2000 gram per liter.

78. Soy protein containing particles according to any of claims 74-77 further characterized by being porous.

79. soy protein containing particles according to any of claims 74-77 further characterized by being solid.

80. soy protein containing particles according to any of claims 74-78 further being characterised by beeing selected from the group consisting of beads, flakes and grains.

81. Use of soy protein containing particles according to any of claims 74-80 as an ingredient in food.

82. Use according to claim 81, wherein the food product is selected from the group consisting of baked products, bread, bars, ground meat, meat balls, drinks, juices, soup or fish.

Figure 1

Comparison of DSC graphs of soy flour and isolate FM on same protein basis, showing the 7S (75-85°C) and 11S (95-105°C) enthalpy peaks.

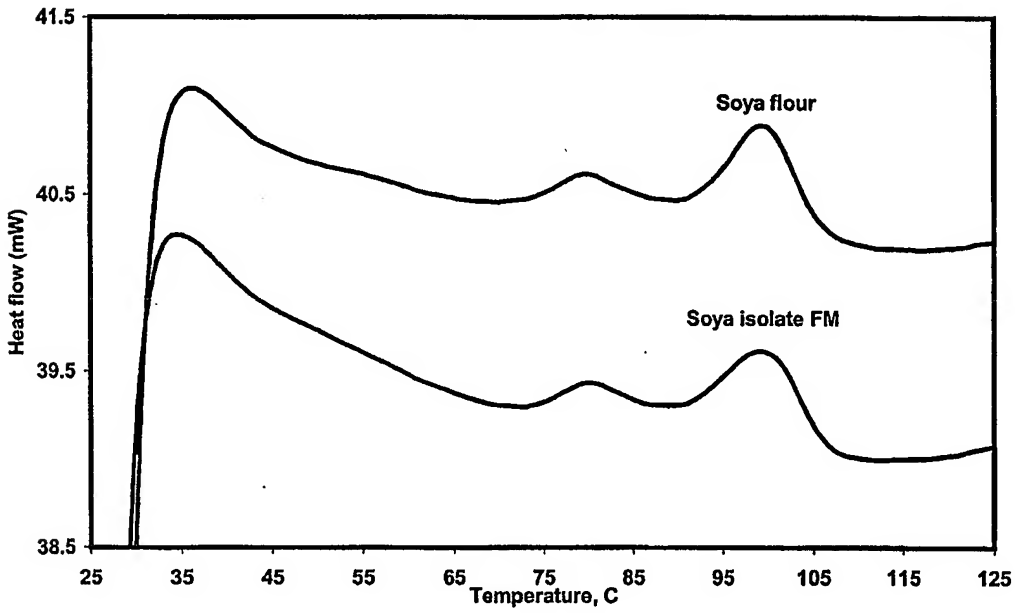
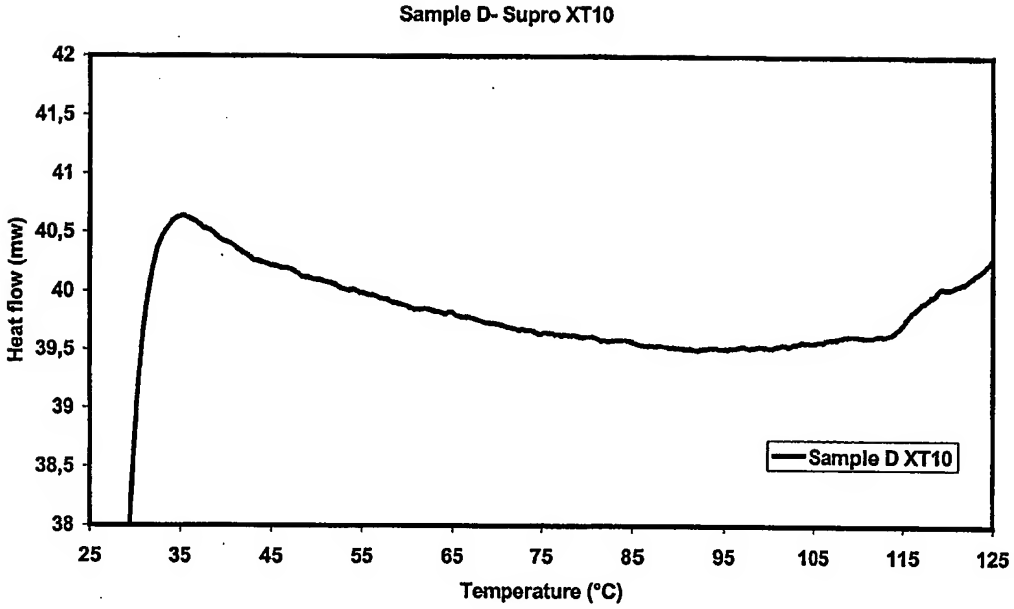
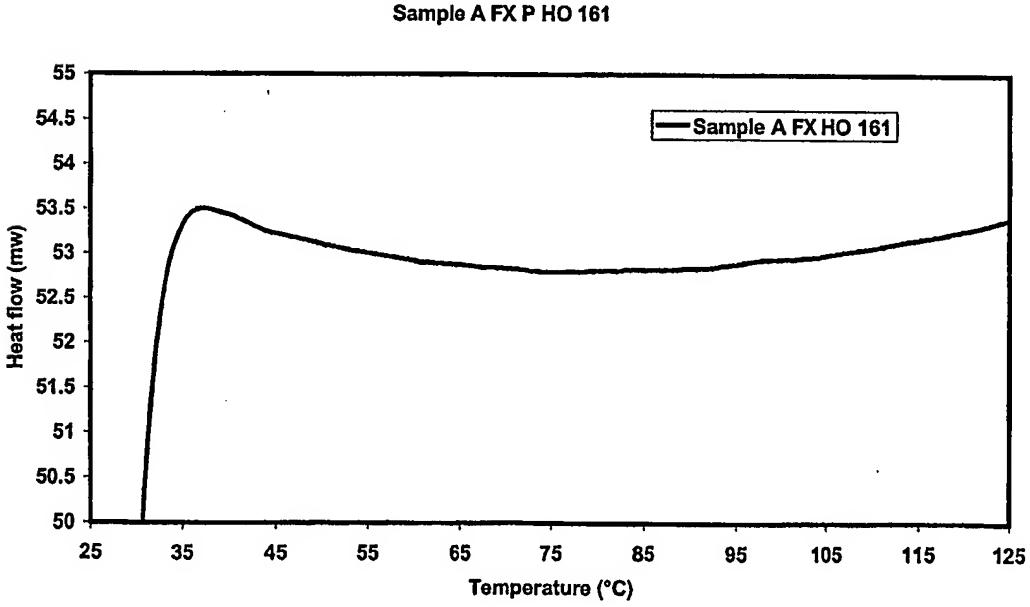


Figure 2


Sample D- Supro XT10
Heat flow (mw)
42
41,5
41
40,5
40
39,5
39
38,5
38
25
35
45
55
65
75
85
95
105
115
125
Temperature (°C)
Sample D XT10


Sample A FX P HO 161
Heat flow (mw)
55
54.5
54
53.5
53
52.5
52
51.5
51
50.5
50
25
35
45
55
65
75
85
95
105
115
125
Temperature (°C)
Sample A FX HO 161